

**THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

THE CITY OF COLUMBUS,) Case No. 2:17-cv-1102
90 W. Broad Street)
Columbus, Ohio 43215) Judge _____
)
 Plaintiff,) **COMPLAINT OF PLAINTIFF THE
) CITY OF COLUMBUS**
)
 v.)
) **JURY DEMAND
 ENDORSED HEREON**
PURDUE PHARMA L.P.)
c/o The Prentice Hall Corporation)
2711 Centerville Road)
Wilmington, DE 19808)
)
 and)
)
PURDUE PHARMA, INC.)
c/o The Prentice Hall Corporation)
2711 Centerville Road)
Wilmington, DE 19808)
)
 and)
)
THE PURDUE FREDERICK COMPANY,)
INC.)
c/o The Prentice Hall Corporation)
2711 Centerville Road)
Wilmington, DE 19808)
)
 and)
)
TEVA PHARMACEUTICALS USA,)
INC.)
c/o Corporate Creations Network Inc.)
3411 Silverside Road)
Wilmington, DE 19180)
)
 and)
)
TEVA PHARMACEUTICAL)
INDUSTRIES, LTD.)
5 Basel Street)
Petach Tikva 49131, Israel)

and)
CEPHALON, INC.)
c/o Corporate Creations Network Inc.)
3411 Silverside Road)
Wilmington, DE 19180)
and)
JOHNSON & JOHNSON)
One Johnson & Johnson Plaza)
New Brunswick, NJ 08933)
and)
JANSSEN PHARMACEUTICALS,)
INC.)
116 Pine Street, Suite 320)
Harrisburg, PA 17101)
and)
JANSSEN PHARMACEUTICA INC.)
N/K/A JANSSEN)
PHARMACEUTICALS, INC.)
116 Pine Street, Suite 320)
Harrisburg, PA 17101)
and)
ORTHO-MCNEIL-JANSSEN)
PHARMACEUTICALS, INC. N/K/A)
JANSSEN PHARMACEUTICALS,)
INC.)
116 Pine Street, Suite 320)
Harrisburg, PA 17101)
and)
NORAMCO, INC.)
c/o The Corporation Trust Company)
Corporation Trust Center)
1209 Orange Street)
Wilmington, DE 19801)
and)

)
ENDO HEALTH SOLUTIONS INC.)
c/o The Corporation Trust Co.)
1209 Orange Street)
Wilmington, DE 19801)
)
and)
)
ENDO PHARMACEUTICALS, INC.)
c/o The Corporation Trust Co.)
1209 Orange Street)
Wilmington, DE 19801)
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and)
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CT Corporation System)
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and)
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ACTAVIS LLC)
Corporate Creations Network, Inc.)
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SCOTT FISHMAN)
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LYNN WEBSTER)
PRA Health Sciences)
3838 S. 700 E. #202)
Salt Lake City, UT 84106)
Defendants.)

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Now comes plaintiff the City of Columbus, Ohio (“Plaintiff,” “City,” “Columbus,” or “City of Columbus”), by and through its attorney, Richard Pfeiffer, City Attorney, for its Complaint against defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries, Ltd.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan plc f/k/a Actavis plc; Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Actavis LLC; and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. (collectively, the “Manufacturers” or “Manufacturer Defendants”); McKesson Corporation; Cardinal Health, Inc.; AmerisourceBergen Drug Corporation (collectively, the “Distributors” or “Distributor Defendants”); Russell Portenoy; Perry Fine; Scott Fishman; and Lynn Webster (collectively, the “Key Opinion Leaders,” “KOLs,” or “KOL Defendants”) (collectively all of the defendants are known as the “Defendants”), alleges as follows:

INTRODUCTION

1. Opioids are a class of drugs that include the illegal drug heroin and synthetic opioids such as fentanyl, oxycodone, hydrocodone, codeine, and many others.¹ Over the last two decades, opioids have become the most prescribed class of drugs in the United States. In 2016, health care providers wrote more than 289 million prescriptions for opioids, or approximately one bottle of pills for every adult in America.²

2. The United States, including the City of Columbus, is in the middle of an opioid addiction epidemic and crisis. Cities like Columbus have been forced to deal with the effects of

¹ See National Institute on Drug Abuse, “Opioids,” <https://www.drugabuse.gov/drugs-abuse/opioids>.

² Prevalence of Opioid Misuse, BupPractice, <https://www.buppractice.com/node/15576>.

prescription and illicit opioid addiction. The Centers for Disease Control and Prevention (“CDC”) estimate that prescription opioid abuse costs the United States \$78.5 billion per year. This includes, but is not limited to, the costs incurred to abate the affects of addiction and addiction-related issues such as increased costs for health care, addiction treatment, and the increased cost to the criminal justice system.³

3. The addiction epidemic is the result of a well-developed marketing scheme by the Manufacturers and KOLs to sell opioids for the treatment of chronic pain. Despite no credible scientific evidence indicating that opioids offer any long-term benefit in treating chronic pain, the Manufacturers and KOLs promoted their opioids as a panacea and pushed billions of pills into communities, including Columbus.

4. The Manufacturers and KOLs misrepresented to other physicians and the public that opioids were a safe treatment for pain with a low risk for addiction, and/or failed to take steps to stem their distribution and flow despite legal duties to do so.

5. Contrary to the representations of safety made by the Manufacturers and the KOLs, there is “[*no evidence*” to show “a long-term benefit of opioids in pain and function versus no opioids for chronic pain.”⁴ ”Extensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury)” and “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder.”⁵

6. The Manufacturers and KOLs spent millions of dollars promoting and marketing opioids to doctors, patients, and the public, including through direct marketing, front groups, medical journals, and unbranded advertising. The Manufacturers and KOLs touted the purported

³ *CDC Foundation’s New Business Pulse Focuses on Opioid Overdose Epidemic*, Centers for Disease Control and Prevention (Mar. 15, 2017), <https://www.cdc.gov/media/releases/2017/a0315-business-pulse-opioids.html>.

⁴ Deborah Dowell, M.D., Tamara M. Haegerich, Ph.D., and Roger Chou, M.D., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, Centers for Disease Control and Prevention (Mar. 18, 2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> (emphasis added).

⁵ *Id.*

benefits of opioids to treat pain and downplayed the risks of addiction related to opioid use. Their representations included, but are not limited to, that there was a low risk of addiction to the Manufacturers' opioids, more opioids should be prescribed to treat pain, risk-mitigation strategies made it safe to prescribe opioids, higher dosages of opioids did not increase risks, abuse-deterrent technology minimized risks, and long-term opioid use improved patients' function and quality of life.

7. The Manufacturers and KOLs generated billions of dollars in sales of opioids. Americans consume 80% of the world's opioid supply and annual prescription opioid sales have consistently approached more than \$10 billion in recent years.

8. The Manufacturers and the KOLs are not the only entities that are liable for the influx of prescription and illicit opioids into Columbus. Once the Manufacturers and the KOLs created the market for opioids, the Distributors helped cause the epidemic by distributing prescription opioids in unprecedented numbers. By failing to report "suspicious" orders, as required by law, the Distributors fueled the growing opioid epidemic, while their profits increased. The Distributors have been suspended and fined multiple times for failing to report "suspicious" orders, including, but not limited to:

- a. On December 23, 2016, Cardinal Health agreed to pay a \$44,000,000 fine to the Department of Justice to resolve the civil penalty portion of administrative action taken against its Lakeland, Florida Distribution Center;
- b. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum of Agreement* with the DEA wherein it agreed to pay a \$150,000,000 civil penalty for violation of the 2008 *Administrative Memorandum of Agreement* with the DEA, as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, La Crosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Court House OH and West Sacramento CA; and

c. On January 6, 2017, AmerisourceBergen agreed to pay \$16,000,000 to the State of West Virginia to resolve claims that AmerisourceBergen acted negligently and unlawfully while engaging in wholesale drug distribution in West Virginia.

9. On September 18, 2017, attorneys general from 41 states announced a joint investigation into the Manufacturers' and Distributors' manufacture, marketing, and distribution of opioids. All eight Manufacturers and Distributors were served with investigative subpoenas and document requests relating to the conduct described herein.⁶

10. As a result of the Defendants' conduct, Columbus has suffered significant harm and damages, including, but not limited to, the breakdown of families, increased health insurance costs, increased police and fire usage, increased usage of the criminal justice system and other significant harms. Columbus also is faced with a significant addiction problem it must abate and remedy.

11. Columbus brings this action to hold the Defendants liable for their conduct in creating and perpetuating the opioid epidemic — conduct that (i) constitutes a public nuisance under Ohio common and statutory law; (ii) constitutes deceptive trade practices under Ohio law; (iii) has injured Columbus through criminal acts; (iv) constitutes fraud under Ohio law; (v) constitutes a pattern of corrupt activity under Ohio law; (vi) constitutes a pattern of racketeering activity under federal law; (vii) constitutes negligence under Ohio law, and (viii) constitutes negligence *per se* under Ohio law.

12. Dr. Andrew Kolodny recently summarized the effect of the Defendants' unlawful scheme:

I think one of the main reasons that we have failed to respond appropriately to the opioid crisis is that it was misframed, and

⁶ Nadia Kounang, CNN, *41 state attorneys general subpoena opioid manufacturers* (Sept. 20, 2017), <http://www.cnn.com/2017/09/19/health/state-ag-investigation-opioids-subpoenas/index.html>.

intentionally so.

* * *

From the beginning of the crisis, the way the issue was framed, particularly by pain organizations – that were getting funding from opioid manufacturers – the way the issue was framed for policymakers was as if all of the bad things that we’re hearing about, all of the opioid harms, policymakers were told, were limited to so called drug abusers, and that millions of patients were being helped by the increase in prescribing.

And so policymakers were told that, your challenge is to try to do something about this drug abuse problem without doing something to the pain problem – millions of Americans are suffering from chronic pain – and if you were to promote any kind of intervention that would result in reduced prescribing, you’ll be punishing the pain patients for the bad behavior of the drug abusers. So you’ve got to balance these two competing problems.

And the reality is that we don’t have these two distinct groups, and *opioids are not safe and effective treatments for the vast majority of people suffering with chronic pain.* Millions of patients with pain have become opioid addicted. Thousands of patients have lost their lives.

* * *

*It’s not an abuse crisis, it’s an addiction epidemic. The reason we have historically high levels of overdose deaths, the reason we’re seeing heroin and fentanyl flood into non-urban areas, the reason we’re seeing a soaring increase in infants born opioid-dependent, children winding up in the foster care system, outbreaks of injection-related infectious diseases, is because we’ve had this very sharp increase in the prevalence, the number of Americans suffering from opioid addiction.*⁷

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §

1331 because the City asserts claims for violations of 18 U.S.C. § 1961, *et seq.* against all

⁷ Dr. Andrew Kolodny, Washington Post Live, Dr. Andrew Kolodny: Opioid crisis ‘not an abuse crisis, it’s an addiction epidemic’ (June 21, 2017), https://www.washingtonpost.com/video/postlive/dr-andrew-kolodny-opioid-crisis-not-an-abuse-crisis-its-an-addiction-epidemic/2017/06/21/789fa53c-568a-11e7-840b-512026319da7_video.html?utm_term=.a6571c16138a (emphasis added).

defendants. In addition, pursuant to 28 U.S.C. § 1367, the Court has supplemental jurisdiction over Columbus' state law claims because they are so related to Columbus' federal claims that they are part of the same case or controversy.

14. This Court has personal jurisdiction over Defendants because they conduct business in Ohio, purposefully direct or directed their actions toward Ohio, consented to be sued in Ohio by registering an agent for service of process, consented to the jurisdiction of Ohio when obtaining a distributor license, and/or have the requisite minimum contacts with Ohio necessary to permit the Court to exercise jurisdiction.

15. Venue is proper in this District pursuant to Southern District of Ohio Local Rule 82.1(c), which provides “[a]n action against a defendant or defendants resident in this District shall be filed at the location of the Court that serves a county in which at least one defendant resides.” *See also* 28 U.S.C. § 1391(c). Defendant Cardinal Health is an Ohio corporation with its principal office located in Dublin, Franklin County, Ohio, which is located in the Eastern Division of the Southern District of Ohio and served by the Columbus location of this Court. Venue is further proper in this District pursuant to 28 U.S.C. §§ 1391, 1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District. 28 U.S.C. §§ 1391(b), 1965(a).

PARTIES

I. PLAINTIFF.

16. The City of Columbus is a municipal corporation organized under Ohio Law. *See* Ohio Constitution, Article XVIII. Columbus has all of the powers of local self-government and home rule and all other powers possible for a city to have under the constitution and laws of the

State of Ohio, which are exercised in the manner prescribed by the charter of the City of Columbus. *See Charter of the City of Columbus; O.R.C. § 715.01.*

17. Columbus is the capital and largest city in the State of Ohio, and is located within Franklin County, Ohio. It is the fourteenth largest city in the United States, with a population of 860,090, according to 2016 Census estimates.

18. Columbus provides a wide range of services on behalf of its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.

19. Columbus has spent, and will continue to spend, significant amounts of taxpayer money combating opioid addiction, including substantial costs for prevention, treatment, law enforcement, prosecution, emergency medical services, probation, and public works. Nearly every department within the City of Columbus, from the Division of Fire to the Recreation and Parks Department, has been forced to devote substantial time, money, and resources to the harm caused by the opioid epidemic.

20. The oversaturation of prescription opioids is a continuing public nuisance. It has caused opioid abuse, addiction, morbidity, and mortality. Columbus is authorized by law to (a) abate any nuisance, (b) prosecute in any court of competent jurisdiction any person who creates, continues, contributes to, or suffers such nuisance to exist, and (c) prevent injury and annoyance from such nuisance. O.R.C. § 715.44; *Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136 (Ohio 2002).

21. Columbus also has standing to recover damages caused by a criminal act. *See* O.R.C. §§ 2307.60, 2307.011(F) (“person” includes “political subdivision”), 2744.01(F) (municipal corporations are “political subdivisions”). Columbus additionally has standing to

bring claims under the Ohio Corrupt Practices Act, and general tort principals. O.R.C. §§ 2923.31(G) (“persons” include governmental entities), 2923.34(A) (“persons” have standing).

II. DEFENDANTS.

A. The Manufacturer Defendants.

22. The Manufacturer Defendants, also referred to herein as “Manufacturers,” are companies whose primary business is the manufacture, marketing and distribution of prescription drugs, including opioids.

23. The Manufacturers have unlawfully orchestrated a marketing and distribution campaign designed to increase sales of opioids throughout the United States, including, but not limited to, in Columbus.

24. The Manufacturers are in the chain of distribution of prescription opioids. The Manufacturers each sold opioids to distributors, including, but not limited to, the Distributors named herein, who distributed them to physicians and pharmacies, including in Columbus. The Manufacturers also improperly distributed opioids that ultimately reached Columbus and its surrounding areas in unlawfully large quantities.

1. Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; and The Purdue Frederick Company, Inc.

25. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. Defendant Purdue Pharma, Inc. is a Delaware corporation with its principal place of business in Stamford, Connecticut. Defendant The Purdue Frederick Company, Inc. is a Delaware corporation with its principal place of business in Stamford, Connecticut. These defendants are collectively referred to herein as “Purdue.” All Purdue entities acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein.

26. Purdue manufactures, promotes, and distributes opioids nationally and in Columbus, including the following drugs: OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER.

27. OxyContin, Butrans, and Hysingla ER are Schedule II and III opioids first approved in 1995, 2010, and 2014, respectively.

28. In the 1990s, Purdue patented, obtained FDA approval for and commercially released OxyContin, an oral formulation of the opioid oxycodone. Oxycodone is chemically related to other opium-derived substances such as morphine, heroin, and hydrocodone.

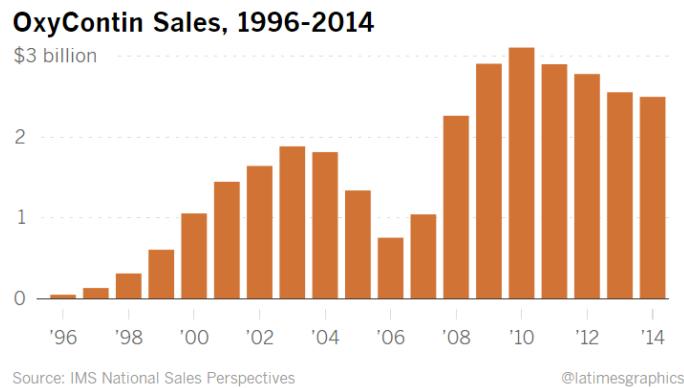
29. Similar to other opioids, oxycodone can be a potent painkiller, but it also has an extremely high potential to become addictive, particularly when used for other than short term use. Because of this, Oxycodone is classified as a Schedule II narcotic under the Controlled Substances Act (“CSA”). Other Schedule II controlled substances include cocaine and methamphetamine.

30. The CSA criminalizes, among other things, the unauthorized distribution and dispensation of substances classified in any of its five schedules. The five schedules are organized from most dangerous (Schedule I) to least dangerous (Schedule V). Classification as Schedule II indicates: (A) the drug or other substance has a high potential for abuse; (B) the drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions; and (C) abuse of the drug or other substances may lead to severe psychological or physical dependence. 21 U.S.C. § 812(b)(2).

31. OxyContin was designed to gradually release its oxycodone content over an extended period of time, with the purported benefit of providing a longer duration of pain relief compared to other oxycodone drugs. Because OxyContin had a higher total oxycodone content

than formulations designed for immediate release, however, the potential for misuse and addiction posed by OxyContin was tremendous.

32. OxyContin is Purdue's largest selling opioid, with national annual sales from 2009 to the present between approximately \$2.5 billion and \$3 billion. OxyContin constitutes approximately 30% of the entire market for analgesic drugs. The following is a chart of OxyContin sales from 1996-2014.⁸



33. By 2009, 81% of the worldwide annual consumption of oxycodone (the opioid used in OxyContin) was used by Americans.⁹

2. Defendants Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries, Ltd.; and Cephalon, Inc.

34. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA is a wholly owned subsidiary of Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation. Defendant Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon.

⁸ John Fauber and Ellen Gabler, Milwaukee Journal Sentinel, *What happened to the poster children of OxyContin?*, <http://archive.jsonline.com/watchdog/watchdogreports/what-happened-to-the-poster-children-of-oxycontin-r65r0lo-169056206.html/>; Los Angeles Times Graphics, *OxyContin Sales, 1996-2014* (May 5, 2016), <http://www.latimes.com/projects/oxycontin-part1/>.

⁹ John Fauber and Ellen Gabler, Milwaukee Journal Sentinel, *What happened to the poster children of OxyContin?*, <http://archive.jsonline.com/watchdog/watchdogreports/what-happened-to-the-poster-children-of-oxycontin-r65r0lo-169056206.html/>.

Collectively, these Defendants are referred to herein as “Teva.”

35. All Teva entities acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein.

36. Teva manufactures several opioids, including Actiq and Fentora, and it promotes, markets, and sells its opioids in Columbus, Ohio.

37. Actiq and Fentora are fentanyl-based opioids. Fentanyl is a synthetic opioid that is 50-100 times more potent than morphine, and 25-50 times more potent than heroin. As a result, Actiq and Fentora are only approved for limited purposes – that is, to treat pain from cancer.

38. Upon information and belief, Teva generates substantial sales from its opioids. In 2005, for example, Teva sold over \$410 million worth of Actiq.¹⁰

**3. Defendants Johnson & Johnson; Janssen Pharmaceuticals, Inc.;
Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.;
Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen
Pharmaceuticals, Inc.; and Noramco, Inc.**

39. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of Defendant Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Noramco, Inc. (“Noramco”) is a Delaware company with its principal place of business in Wilmington, Delaware, and was a wholly-owned subsidiary of Johnson &

¹⁰ John Carreyrou, The Wall Street Journal, “Narcotic ‘Lollipop’ Becomes Big Seller Despite FDA Curbs” (Nov. 3, 2006), <https://www.wsj.com/articles/SB116252463810112292>.

Johnson until July 2016. Collectively, these entities are referred to herein as “Janssen.”

40. All Janssen entities acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein.

41. Johnson & Johnson owns more than 10% of Janssen Pharmaceuticals, Inc., and, upon information and belief, communicates with the FDA regarding the drugs manufactured by Janssen Pharmaceuticals, Inc. Upon information and belief, Johnson & Johnson controls the sale and development of the drugs manufactured by Janssen Pharmaceuticals, Inc.

42. Janssen manufactures, promotes, sells, markets, and distributes opioids such as Duragesic, Nucynta, and Nucynta ER in the United States, including in Columbus, Ohio.

43. Janssen stopped manufacturing Nucynta and Nucynta ER in 2015.

44. Duragesic and Nucynta ER are Schedule II opioids first approved in 1990 and 2011, respectively.

45. Janssen generates substantial revenue from its opioids. Janssen sold more than \$1 billion of Duragesic in 2009, and sold \$172 million worth of Nucynta and Nucynta ER in 2014.

4. Defendants Endo Health Solutions Inc. and Endo Pharmaceuticals, Inc.

46. Defendant Endo Pharmaceuticals, Inc. is a wholly owned subsidiary of Defendant Endo Health Solutions Inc. Both are Delaware corporations with their principal place of business in Malvern, Pennsylvania. Collectively, these entities are referred to as “Endo.”

47. Each Endo entity acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein.

48. Endo manufactures, promotes, sells, markets, and distributes opioids such as Percocet, Percodan, Opana, and Opana ER in the United States, including in Columbus.

49. Endo generates substantial revenue from its opioids. Endo sold more than \$400

million in 2012, and sold more than \$1 billion of Opana ER 2010 to 2013.

5. Defendants Allergan plc f/k/a Actavis plc; Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Actavis LLC; and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.

50. Defendant Allergan plc f/k/a Actavis plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis plc acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in March 2015. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Defendant Actavis Pharma, Inc. f/k/a Actavis, Inc. is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Collectively, these entities are referred to as the “Actavis Defendants” or “Actavis.”

51. Each Actavis entity acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts, and profits from the sale of Actavis products ultimately inure to its benefit.

52. Actavis manufactures, promotes, sells, markets, and distributes opioids such as Kadian and Norco, and several generic opioids, and it promotes, markets, and sells its opioids in Columbus.

53. Upon information and belief, Actavis generates substantial sales from its opioids.

B. The Distributor Defendants.

54. The Distributor Defendants, also collectively referred to herein as the “Distributors,” are in the chain of distribution of prescription opioids, namely hydrocodone and oxycodone. Upon information and belief, the Distributors have distributed the Manufacturers’ opioids to Columbus physicians and pharmacies.

1. Defendant McKesson Corporation.

55. Defendant McKesson Corporation (“McKesson”) is registered with the Ohio Secretary of State as a Delaware corporation and may be served through its registered agent for service of process, Corporation Service Company, 50 West Broad Street, Suite 1330, Columbus, Ohio 43215. McKesson’s principal place of business is located in San Francisco, California. McKesson operates distribution centers in Ohio, including in Washington Court House, Ohio.

2. Defendant Cardinal Health, Inc.

56. Defendant Cardinal Health, Inc. is registered with the Ohio Secretary of State as an Ohio corporation, with its principal place of business located in Dublin, Ohio, and may be served through its registered agent for service of process, CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, Ohio 43219. Cardinal Health operates distribution centers nationwide and in Ohio, including in Groveport, Ohio and in Zanesville, Ohio.

3. Defendant AmerisourceBergen Drug Corporation.

57. Defendant AmerisourceBergen Drug Corporation (“AmerisourceBergen”) is registered with the Ohio Secretary of State as a Delaware corporation and may be served through its registered agent for service of process, CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, Ohio 43219. AmerisourceBergen’s principal place of business is located in Chesterbrook, Pennsylvania. AmerisourceBergen operates distribution centers in Ohio,

including in Lockbourne, Ohio.

C. Defendants Russell Portenoy; Perry Fine; Scott Fishman; And Lynn Webster.

58. Defendants Russell Portenoy; Perry Fine; Scott Fishman; and Lynn Webster are Key Opinion Leaders or “KOLs.” “Key Opinion Leaders” is a pharmaceutical industry term of art meaning “physicians who influence their peers’ medical practice, including but not limited to prescribing behavior.”¹¹

59. The KOLs were paid by the Manufacturers to tout misrepresentations regarding the risks and benefits of opioids. The KOLs knowingly misrepresented that opioids could be used effectively to treat conditions such as chronic pain, and downplayed the risks of addiction and abuse.

1. Defendant Russell Portenoy.

60. Defendant Russell Portenoy, M.D., is a citizen of New York. Dr. Portenoy is a physician licensed to practice medicine in the state of New York. Dr. Portenoy promoted opioids for sale and distribution nationally and in Columbus.

61. For the past two decades, multiple Manufacturers have paid Dr. Portenoy to make representations regarding opioids and addiction in general.¹²

62. Dr. Portenoy served on the American Pain Society (“APS”)/American Academy of Pain Medicine (“AAPM”) Guidelines Committees, which misrepresented the use of opioids as

¹¹ See Pharma Marketing Network, The Pharma Marketing Glossary, “Key Opinion Leader (KOL)” (2014), <http://www.pharma-mktng.com/glossary/keyopinionleader.htm>.

¹² Peter Whoriskey, The Washington Post, *Rising painkiller addiction shows damage from drugmakers' role in shaping medical opinion* (Dec. 30, 2012), https://www.washingtonpost.com/business/economy/2012/12/30/014205a6-4bc3-11e2-b709-667035ff9029_story.html?utm_term=.351a72fdd485 (As of 2002, Dr. Portenoy “reported involvements on contracts and grants with Parke-Davis, Boehringer Ingelheim, Elan, Ortho Biotech, Endo, Ametek, Medtronic, Purdue Pharma, Pfizer, Janssen, Abbott, Curatech, Ortho-McNeil and Searle.”); see also Janice Lynch Schuster, MedPage Today, *Portenoy Opioid Talk Sparks Controversy* (Sept. 28, 2014), <https://www.medpagetoday.com/painmanagement/painmanagement/47855>. Additionally, Dr. Portenoy received payments from Teva Pharmaceuticals in 2015. See, e.g., Open Payments federal database, <https://openpaymentsdata.cms.gov/physician/886802/payment-information>.

an effective treatment for chronic pain.

63. Dr. Portenoy also was a member of the board of the American Pain Foundation (“APF”), an organization funded by the Manufacturers. He served as the director of APF in the late 1990s, and campaigned to make pain the “fifth vital sign” that doctors needed to monitor, along with blood pressure, temperature, breathing, and heartbeat.

2. Defendant Perry Fine.

64. Defendant Perry Fine, M.D., is a citizen of Utah. Dr. Fine promoted opioids for sale and distribution nationally and in Columbus.

65. Dr. Fine served on the board of directors of APF alongside Defendant Scott Fishman. APF was financed by Manufacturers and issued education guides that promoted the benefits of opioids for chronic pain, while trivializing their risks, particularly the risk of addiction.

3. Defendant Scott Fishman.

66. Defendant Scott Fishman, M.D., is a citizen of California. Dr. Fishman promoted opioids for sale and distribution nationally and in Columbus.

67. Dr. Fishman authored *Responsible Opioid Prescribing: A Physician’s Guide*, a book funded, at least in part, by certain of the Manufacturers, including Endo. Those Manufacturers attempted to distribute the book to all 700,000 doctors in the United States.¹³

4. Defendant Lynn Webster.

68. Defendant Lynn Webster, M.D., is an anesthesiologist and a citizen of Utah. Dr. Webster promoted opioids for sale and distribution nationally and in the city of Columbus.

69. Dr. Webster is a current board member of AAPM, a front group that supports

¹³Milwaukee Journal Sentinel, *Drug company influence: A case study*, <http://archive.jsonline.com/features/health/drug-company-influence-a-case-study-139610013.html>.

chronic opioid therapy.

70. Like Dr. Portenoy, multiple Manufacturers used Dr. Webster as a KOL and provided him with funding and consultant fees. Dr. Webster authored numerous Continuing Medical Education (“CME”) materials sponsored by Teva, Endo, and Purdue. At the same time, Dr. Webster received significant funding from the Manufacturers (including nearly \$2 million from Teva).¹⁴

71. Dr. Webster also promoted the concept of “pseudoaddiction” as a theory that addictive behaviors were indications of undertreated pain, and should not be viewed as warnings of addiction. According to Dr. Webster, in a book he co-authored entitled *Avoiding Opioid Abuse While Managing Pain*, when faced with “drug seeking behavior,” the “clinician’s first response” should be to increase the dose.¹⁵

FACTS RELEVANT TO ALL CAUSES OF ACTION

I. THE OPIOID EPIDEMIC CREATED BY THE MANUFACTURERS, THE DISTRIBUTORS AND THE KOLS, CAUSED, AND CONTINUES TO CAUSE, DEVASTATION, HARM AND DAMAGES TO COLUMBUS.

72. Opioids are a class of drugs used to treat pain. They are derived in whole or in part from the opium poppy, the same plant from which morphine and heroin are made. Some opioids also are completely synthetic, but nevertheless contain the same properties as morphine and heroin.

73. The term “opioid” refers to natural, synthetic, and semi-synthetic opioids. The Manufacturers manufacture synthetic and semi-synthetic opioids. Opium and morphine are examples of natural opioids.

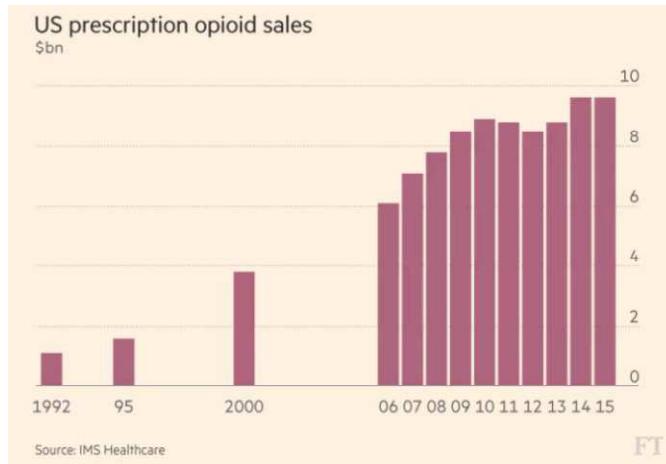
¹⁴ Kristen Stewart & Jennifer Dobner, The Salt Lake Tribune, *Utah doctors paid \$25.8 million by drug companies* (March 12, 2013), <http://archive.sltrib.com/article.php?id=55962410&itype=CMSID> (Noting “[o]nly three other doctors in the country received more [money] from [Teva]” than Dr. Webster.)

¹⁵ Webster, Lynn R., and Beth Dove. “Chapter III.” *Avoiding Opioid Abuse While Managing Pain: a Guide for Practitioners*, Sunrise River Press, 2007.

74. Opioids are highly addictive, habit-forming drugs, something the medical community has understood for centuries. Until the 1990s, medical professionals employed opioid-based drugs with caution, prescribing them in limited circumstances to patients with cancer, terminal illnesses, or acute short-term pain.

75. Opioid use has increased in the last twenty years. Opioids are now commonly prescribed for general pain. One in every five patients with non-cancer pain symptoms or pain-related diagnoses is prescribed opioids.¹⁶

76. Over the past two decades, annual opioid prescription sales have increased from approximately \$1 billion to \$10 billion:¹⁷



77. Between 1991 and 2011, opioid prescriptions in the U.S. tripled, from 76 million to 219 million per year.¹⁸ In 2016, there were more than 289 million prescriptions for opioids filled in the U.S.¹⁹

¹⁶ Deborah Dowell, M.D., Tamara M. Haegerich, Ph.D., and Roger Chou, M.D., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, Centers for Disease Control and Prevention (Mar. 18, 2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

¹⁷ David Crow, *Drugmakers hooked on \$10bn opioid habit*, Financial Times (Aug. 10, 2016), <https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95?mhq5j=e1>.

¹⁸ Nora D. Volkow, MD, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, Appearing before the Senate Caucus on International Narcotics Control, NIH National Institute on Drug Abuse (May 14, 2014), <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse>.

¹⁹ Prevalence of Opioid Misuse, BupPractice, <https://www.buppractice.com/node/15576> (last visited Sept. 7, 2017).

78. By 2012, one in three opioid users was prescribed dosages of opioids that rendered them more potent than morphine.²⁰

79. The Manufacturers and the KOLs aggressively pushed the use of opioids to physicians in general. The majority of medical professionals who prescribe opioids are not pain specialists. A 2014 study concluded that of the more than half million prescribers of opioids during that time period, only 385 were identified as pain specialists.²¹

80. The increase in opioid prescriptions has caused a national epidemic and nuisance. From 1999 to 2015, the number of opioid overdose deaths increased from approximately 4,030 to more than 33,000.²²

81. More than 183,000 deaths from prescription opioids have been reported in the United States since 1999.²³ Someone in the U.S. dies from an overdose of a prescription opioid every sixteen minutes.²⁴

82. Between 2000 and 2015, life expectancy in the United States increased overall, but drug-poisoning deaths, mostly related to opioids, contributed to reducing life expectancy.²⁵

²⁰ *America's opioid epidemic is worsening*, the Economist (Mar. 6, 2017), <https://www.economist.com/blogs/graphicdetail/2017/03/daily-chart-3>.

²¹ *A Nation in Pain*, Express Scripts (Dec. 9, 2014), <http://lab.express-scripts.com/lab/publications/a-nation-in-pain>.

²² *Overdose Death Rates*, NIH National Institute on Drug Abuse, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> (revised Jan. 2017). The actual number of opioid-related deaths is likely much higher. As much as 25 percent of the time, death certificates do not record the drug responsible for an overdose. See Centers for Disease Control and Prevention, Opioid Data Analysis (Feb. 9, 2017), <https://www.cdc.gov/drugoverdose/data/analysis.html> (“[A]ll the numbers are likely to underestimate the true burden given the large proportion of overdose deaths where the type of drug is not listed on the death certificate.”); Alexandra Sifferlin, Time, “Dying From an Opioid Overdose Is More Common Than You Think” (Aug. 7, 2017), <http://time.com/4890536/opioid-heroin-overdose-deaths/> (“Between 20%-25% of the overdose death certificates Ruhm studied did not have any drug specified, suggesting that statewide estimates of deaths linked to opioids could be significantly off.”).

²³ *Understanding the Epidemic*, Centers for Disease Control and Prevention, <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last updated Aug. 30, 2017).

²⁴ Katelyn Newman, U.S. News, From Punishing Users to Treating a Disease (May 18, 2017), <https://www.usnews.com/news/national-news/articles/2017-05-18/the-opioid-epidemic-from-punishing-users-to-treating-a-disease>.

²⁵ Rachel Becker, The Verge, *The opioid epidemic is so bad it's driving down life expectancy in the US*, <https://www.theverge.com/2017/9/19/16333126/opioid-epidemic-deaths-us-national-life-expectancy-emergency-cdc-jama-research>.

The rising death rate from drug overdoses during the same time period cut the average life expectancy in the United States by more than three months – roughly the same reduction attributable to rising death rates from injuries, Alzheimer’s disease, suicide, chronic liver disease, and sepsis *combined*.²⁶

83. Unintentional drug overdoses are the leading cause of injury-related death in Ohio, ahead of motor vehicle traffic crashes. This trend began in 2007.²⁷ Of the 4,050 Ohioans who died of unintentional drug overdoses in 2016, 86.3% overdosed on opioids – far above the national average.²⁸ Persons addicted to opioids are less productive.

84. The total economic loss attributable to prescription opioids is at least \$78.5 billion per year.²⁹ At least one quarter of these costs – approximately \$20 billion per year – are borne by the public sector, including by municipalities like Columbus.³⁰

II. THE MANUFACTURERS, DISTRIBUTORS AND KOLS CAUSED THE OPIOID EPIDEMIC.

85. The safe and effective treatment of chronic pain requires physicians to weigh the risks of prescribing opioids against the benefits, as well as the risks and benefits of alternative treatments. Thus, physicians need to be given accurate information about opioids.

A. It Was Generally Accepted That Long-Term Use Of Opioids Was Considered Risky.

86. The DEA has regulated opioids as controlled substances since 1970.

87. In the 1970s, 1980s and prior, it was the generally accepted view throughout the medical community that opioids should not be used for long-term treatment of chronic pain

²⁶ *Id.*

²⁷ Ohio Department of Health, *2016 Ohio Drug Overdose Data: General Findings* (2016), <https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/2016-Ohio-Drug-Overdose-Report-FINAL.pdf?la=en>

²⁸ *Id.*

²⁹ *CDC Foundation’s New Business Pulse Focuses on Opioid Overdose Epidemic*, Centers for Disease Control and Prevention (Mar. 15, 2017), <https://www.cdc.gov/media/releases/2017/a0315-business-pulse-opioids.html>.

³⁰ Wolters Kluwer Health: Lippincott Williams and Wilkins, *Costs of US prescription opioid epidemic estimated at \$78.5 billion*, *Science Daily* (Sept. 14, 2016), <https://www.sciencedaily.com/releases/2016/09/160914105756.htm>.

because opioids were not effective and did not improve function. Patients also developed tolerance and addiction issues.³¹

88. As a result, before the 1990s, long held and generally accepted standards of medicine dictated that opioids only should be used short-term, for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. The use of opioids to treat chronic pain was discouraged or prohibited because there was: (a) a lack of evidence that opioids improved patients' ability to overcome pain and still function; (b) evidence of greater pain complaints as patients developed tolerance to opioids over time; and (c) serious risk of addiction and other side effects. In addition to physical and psychological dependency, it was believed that chronic therapy produced greater psychological distress, poorer outcomes, and impaired cognition.³²

B. Opioids Are Highly Addictive.

89. Prescribing opioids, even for short term pain, risks addiction.

90. 30% to 40% of long-term users of opioids experience opioid use disorders.³³

According to the Substance Abuse and Mental Health Services Administration (“SAMHSA”), symptoms of opioid use disorders include a “strong desire for opioids, inability to control or reduce use, continued use despite interference with major obligations or social functioning, use of larger amounts over time, development of tolerance, spending a great deal of time to obtain and use opioids, and withdrawal symptoms that occur after stopping or reducing use, such as

³¹ Sonia Moghe, CNN, *Opioid History: From ‘wonder drug’ to abuse epidemic* (Oct. 14, 2016), <http://www.cnn.com/2016/05/12/health/opioid-addiction-history/index.html> (“By the mid- and late-1970s, when Percocet and Vicodin came on the market, doctors had long been taught to avoid prescribing highly addictive opioids to patients.”).

³² See, e.g., Maruta, T. and Swanson, D.W., Problems With The Use Of Oxycodone Compound In Patients With Chronic Pain, *Pain*, 11 (1981), 389-396.

³³ Joseph A. Boscarino et al., *Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system*, 105(10) *Addiction* 1776 (2010), http://www.thblack.com/links/RSD/Addiction2010_105_1776_RiskFactors4Depend.pdf.

negative mood, nausea or vomiting, muscle aches, diarrhea, fever, and insomnia.”³⁴

91. After taking opioids for a period of time, patients develop a tolerance to their pain relieving effects. As a result, patients typically require increased doses to achieve the original pain relief. These doses can become “frighteningly high.”³⁵ As doses increase, the withdrawal symptoms increase, making a patient more susceptible to addiction. Patients can even overdose on recommended doses. Fear of withdrawal symptoms can force a patient to seek additional opioids to avoid the adverse consequences of withdrawal.³⁶

C. There Is No Credible Evidence To Support Long-Term Opioid Use For Chronic Pain.

92. There are no credible studies that support the long-term effectiveness of opioids for patients with chronic non-cancer pain.³⁷

93. By 2009, the Journal of Pain (the official journal of the APS) noted:

Critical research gaps on use of opioids for chronic noncancer pain include: lack of effectiveness studies on long-term benefits and harms of opioids (including drug abuse, addiction, and diversion); insufficient evidence to draw strong conclusions about optimal approaches to risk stratification, monitoring, or initiation and titration of opioid therapy; and lack of evidence on the utility of informed consent and opioid management plans, the utility of opioid rotation, the benefits and harms specific to methadone or higher doses of opioids, and treatment of patients with chronic noncancer pain at higher risk for drug abuse or misuse.³⁸

94. Studies have shown that there is no, or limited, efficacy for the use of opioids to

³⁴ Substance Abuse and Mental Health Services Administration, “Substance Use Disorders” (Oct. 27, 2015), <https://www.samhsa.gov/disorders/substance-use>.

³⁵ M. Katz, Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith, 170(16) Archives of Internal Med. 1422 (2010).

³⁶ See, e.g., Geordan Omand, The Globe and Mail, *Longtime opioid users motivated by fear of withdrawal* (Last updated March 24, 2017), <https://www.theglobeandmail.com/news/british-columbia/longtime-opioid-users-motivated-by-fear-of-withdrawal/article33360222/> (“[O]ne of the primary motivators for people to continue using drugs is to relieve or avoid withdrawal.”).

³⁷ Roger Chou, et al., Journal of Pain, Volume 10, Issue 2, 149-155, *Research Gaps on Use of Opioids for Chronic Noncancer Pain: Findings From a Review of the Evidence for an American Pain Society and American Academy of Pain Medicine Clinical Practice Guide* (Feb. 2009), [http://www.jpain.org/article/S1526-5900\(08\)00830-4/fulltext](http://www.jpain.org/article/S1526-5900(08)00830-4/fulltext).

³⁸ *Id.*

treat chronic back pain, non-cancer pain, and headaches.³⁹

95. Opioids do not improve patients' function. "For functional outcomes, the other analgesics were significantly more effective than were opioids."⁴⁰

96. Contrary to his later work for the Manufacturers, in 1986, Defendant Dr. Russell Portenoy, a KOL and top spokesperson for the Manufacturers, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."⁴¹

97. Also contrary to his later work for the Manufacturers, upon information and belief, in 1994, Dr. Portenoy described the dangers of long-term use of opioids, including problems with drug seeking behavior and addiction.

98. Also contrary to his later work for Manufacturers, upon information and belief,

³⁹ K.C. Brennan, et al., Neurology, *Symptom Codes And Opioids: Disconcerting Headache Practice Patterns In Academic Primary Care* (April 8, 2015), abstract http://www.neurology.org/content/82/10_Supplement/S41.003.short; Robert P. Cowan, MD, American Migraine Foundation, "Opioid Narcotics and Headache" (July 29, 2015), <https://americanmigrainefoundation.org/understanding-migraine/opioid-narcotics-and-headache/>; Bridget A. Martell et al., Annals of Internal Medicine, *Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction* (2007), https://www.researchgate.net/profile/Robert_Kerns/publication/6574580_Systematic_Review_Opioid_Treatment_for_Chronic_Back_Pain_Prevalence_Efficacy_and_Association_with_Addiction/links/00b7d530c87b9ea0d4000000/Systematic-Review-Opioid-Treatment-for-Chronic-Back-Pain-Prevalence-Efficacy-and-Association-with-Addiction.pdf ("On the basis of recent attention to the treatment for pain and concerns regarding the adverse effects of nonsteroidal anti-inflammatory medications, it would be expected that an increasing number of patients with chronic back pain will receive opioid medications. The findings in this review suggest that clinicians should reconsider treating chronic back pain with opioid medications, and consider other treatments with similar benefit yet fewer long-term adverse effects.").

⁴⁰ Andrea D. Furlan, et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (2006), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459894/pdf/20060523s00017p1589.pdf>. This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are prescreened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. Karen H. Seal, *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940 (2012), https://www.researchgate.net/publication/221683297_Association_of_Mental_Health_Disorders_With_Prescription_Opioids_and_High-Risk_Opioid_Use_in_US_Veterans_of_Iraq_and_Afghanistan; Andrea Rubenstein, *Are we making pain patients worse?*, Sonoma Medicine (Fall 2009), <http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747>.

⁴¹ Russell K. Portenoy & Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25(2) Pain 171 (1986).

Dr. Portenoy stated that there was a lack of evidence supporting the safety and efficacy of opioid therapy for long-term chronic non-cancer pain as of 1994.

99. The longer a patient uses opioids, the more likely they are to suffer mental health conditions, experience increased psychological distress, and seek medical attention more frequently.

D. The Manufacturers' And KOLs' Marketing Scheme Changed The Perception About, And Prescribing Of, Opioids.

100. Prior to the conduct of the Manufacturers and the KOLs described herein, generally accepted medical standards held that opioids only should be used short-term or for cancer or palliative care.

101. Internal Purdue documents reveal, for example, that even before OxyContin was released, Purdue's goal was clear: "we do **not** want to niche OxyContin just for cancer pain."⁴² Purdue also insisted that "there is a big non-cancer marketplace for OxyContin."⁴³

102. Upon information and belief, Actavis commissioned a consulting report in 2005, in anticipation of releasing Kadian to the market. Upon information and belief, that report concluded that two challenges facing opioid manufacturers were: (1) overcoming concerns of opioids; and (2) that physicians are hesitant to change prescribing patterns without supporting data. Upon information and belief, Actavis designed its marketing of Kadian to circumvent these two challenges.

103. Notwithstanding their actual and constructive knowledge of the negative impact of opioids, the Manufacturers and the KOLs used multiple means to mislead doctors and the general public into believing that long-term use of opioids was an effective and safe treatment

⁴² Los Angeles Times, OxyContin Files, "Launch Team Meeting 3/31/95 Minutes," (April 4, 1995) <http://documents.latimes.com/oxycontin-launch-1995/> (emphasized in original).

⁴³ *Id.*

for chronic pain. As a spokesperson for the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), testified before Congress, “aggressive marketing by pharmaceutical companies” is a cause of the opioid abuse problem.⁴⁴

1. The Manufacturers directly misrepresented to physicians the risks and benefits of prescription opioids.

104. The Manufacturers communicated directly to doctors through in-person communications from sales representatives, CMEs, and other written literature.

105. The Manufacturers spent hundreds of millions of dollars to communicate their misleading messages to doctors.⁴⁵ The Manufacturers employed sales representatives to present their message to doctors and to increase both the volume of opioids sold and promote the prescription of higher doses of opioids.⁴⁶ Purdue increased its internal sales force from 318 to 671 and almost doubled its physician call list from 1996 to 2000.⁴⁷ The Manufacturers provided substantial bonuses to their salespersons to increase their sales. For example, Purdue paid \$40 million in bonuses to its salespersons in 2001.⁴⁸

106. The Manufacturers also invited doctors to attend free pain conferences at resorts in warm-weather locations. More than 5,000 medical professionals attended those trips from 1996-2001.⁴⁹ At these conferences, the Manufacturers promoted the long-term use of opioids for long-term treatment of chronic pain. These free trips and seminars influenced doctors to increase

⁴⁴ Nora D. Volkow, MD, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, Appearing before the Senate Caucus on International Narcotics Control, NIH National Institute on Drug Abuse (May 14, 2014), <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse>.

⁴⁵ Mike Mariani, *How the American opiate epidemic was started by one pharmaceutical company*, The Week (Mar. 4, 2015), <http://theweek.com/articles/541564/how-american-opiate-epidemic-started-by-pharmaceutical-company>.

⁴⁶ Los Angeles Times, *Letter to Sales Reps, 1996*, May 5, 2016, <http://documents.latimes.com/letter-sales-reps-1996/>. At the time, 40mg was the largest pill of OxyContin available.

⁴⁷ Art Van Zee, M.D., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J Public Health 221-27 (Feb. 2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf>.

⁴⁸ *Id.*

⁴⁹ *Id.*

the number of prescriptions of opioids for chronic pain. Doctors attending the seminars were twice as likely to write prescriptions for opioids as those who did not.⁵⁰

107. The Manufacturers also spent, upon information and belief, hundreds-of-thousands, if not millions, of dollars to review and analyze data from IMS Health Holdings, Inc. to determine which doctors prescribed opioids and the volume of those prescriptions. The use and analysis of the data became the bedrock of the Manufacturers' marketing campaigns and allowed the Manufacturers to tailor their communications with each doctor.⁵¹ Upon information and belief, the Manufacturers continue to employ the same marketing practices today.

108. The Manufacturers targeted family and primary care doctors that were susceptible to their marketing campaigns because they were not pain specialists and were more likely to rely on the information provided by the Manufacturers.⁵² As a result of the Manufacturers' marketing campaign, doctors relied on the materials provided by the Manufacturers and prescribed opioids for chronic pain.

2. The Manufacturers funded, controlled and operated third-party organizations that made misrepresentations to physicians about the risks and benefits of opioids.

109. The Manufacturers funded and controlled organizations that communicated to doctors, patients, and the public about the purported benefits of opioids to treat chronic pain. These organizations were known as "Front Groups" and they published prescribing guidelines, unbranded materials, and other programs that promoted opioids for chronic pain. The Front Groups sought to influence not only doctors and patients, but lawmakers as well, to increase the number of opioid prescriptions written.

⁵⁰ Harriet Ryan, Lisa Girion and Scott Glover, *OxyContin goes global — "We're only just getting started"*, Los Angeles Times (Dec. 18, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part3/>.

⁵¹ Art Van Zee, M.D., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J Public Health 221-27 (Feb. 2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/pdf/221.pdf>.

⁵² *Id.*

110. For example, APF received more than \$10 million from opioid drug manufacturers, including, upon information and belief, Purdue, Endo, Teva, and Janssen, between 2007 and 2012.⁵³ APF's operating budget was comprised almost entirely of contributions from prescription opioid manufacturers. Not only did the Manufacturers control APF's finances, its board of directors was full of doctors who were on the Manufacturers' payrolls.⁵⁴ APF also lobbied against federal and state proposals to limit opioid use.⁵⁵

111. The AAPM, which received more than \$2.2 million in funding since 2009 from opioid drug manufacturers, including, upon information and belief, Purdue, Endo, Teva, and Actavis, held itself out as an independent and non-biased advocacy group representing physicians practicing in the field of pain medicine.⁵⁶ In fact, the AAPM simply was another Front Group used by the Manufacturers.⁵⁷ The AAPM participated in issuing guidelines in 2009 entitled "Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain – Evidence Review" ("2009 Guidelines"), which misrepresented that opioids were "safe and effective" for treating chronic pain. The 2009 Guideline is still available online today.⁵⁸

112. The Manufacturers realized treatment guidelines can "change prescribing practices," by falsely giving the appearance that it was an unbiased source of evidence-based information, even though they were really marketing materials.

⁵³ Charles Ornstein and Tracy Weber, *The Champion of Painkillers*, ProPublica (Dec. 23, 2011), <https://www.propublica.org/article/the-champion-of-painkillers>.

⁵⁴ *Id.*

⁵⁵ See Matthew Perrone, The Center For Public Integrity, *Pro-painkiller echo chamber shaped policy amid drug epidemic* (December 15, 2016), <https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic>.

⁵⁶ Larry McShane, NY Daily News, "How Big Tobacco-style marketing propels U.S. opioid crisis" (June 24, 2017), <http://www.nydailynews.com/news/national/big-tobacco-style-marketing-propels-u-s-opioid-crisis-article-1.3274960>.

⁵⁷ Tracy Weber and Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011), <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry>.

⁵⁸ *Clinical Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, American Pain Society, <http://americanpainsociety.org/uploads/education/guidelines/chronic-opioid-therapy-cncp.pdf> (last visited Sept. 7, 2017).

113. Upon information and belief, the Manufacturers participated in the Pain Care Forum, a coalition of drug makers, trade groups, and nonprofit organizations, which spent more than \$740 million lobbying in the nation's capital and all fifty states on an array of issues, including opioid-related measures.⁵⁹

114. Another group, a University of Wisconsin-based organization known as the Pain & Policy Studies Group, received about \$2.5 million from pharmaceutical companies, including, but not limited to, Purdue, to promote opioid use and discourage the passing of regulations against opioid use in medical practice.⁶⁰ The Pain & Policy Studies Group wields considerable influence over the nation's medical schools.⁶¹ Purdue was the largest contributor to the Pain & Policy Studies Group, paying approximately \$1.6 million between 1999 and 2010.⁶²

115. The Manufacturers also engaged in unbranded advertising to generally tout the benefits of opioids without specifically naming a particular brand of opioid. Unbranded marketing promotes a type of treatment generally, and is typically not reviewed by the FDA.

3. The Manufacturers retained the KOLs to conceal their misrepresentations about the risks and benefits of opioids in the guise of credentialed medical professionals.

116. The Manufacturers compensated the KOLs, who misrepresented the benefits of opioid use for chronic pain at CME seminars and conferences. The KOLs misrepresented that they were independent of the Manufacturers. In fact, the KOLs served on advisory boards of the Manufacturers, on the boards of certain Front Groups, and on committees that helped develop

⁵⁹ Matthew Perrone and Ben Wieder, *Pro-painkiller echo chamber shaped policy amid drug epidemic*, AP News (Sept. 19, 2016), <https://apnews.com/3d257452c24a410f98e8e5a4d9d448a7/pro-painkiller-echo-chamber-shaped-policy-amid-drug>.

⁶⁰ John Fauber, Journal Sentinel, *UW group ends drug firm funds* (April 20, 2011), <http://archive.jsonline.com/watchdog/watchdogreports/120331689.html>.

⁶¹ *The Role of Pharmaceutical Companies in the Opioid Epidemic*, Addictions.com, <https://www.addictions.com/opiate/the-role-of-pharmaceutical-companies-in-the-opioid-epidemic/> (last visited Sept. 7, 2017).

⁶² John Fauber, *UW group ends drug firm funds*, Journal Sentinel (Apr. 20, 2011), <http://archive.jsonline.com/watchdog/watchdogreports/120331689.html>.

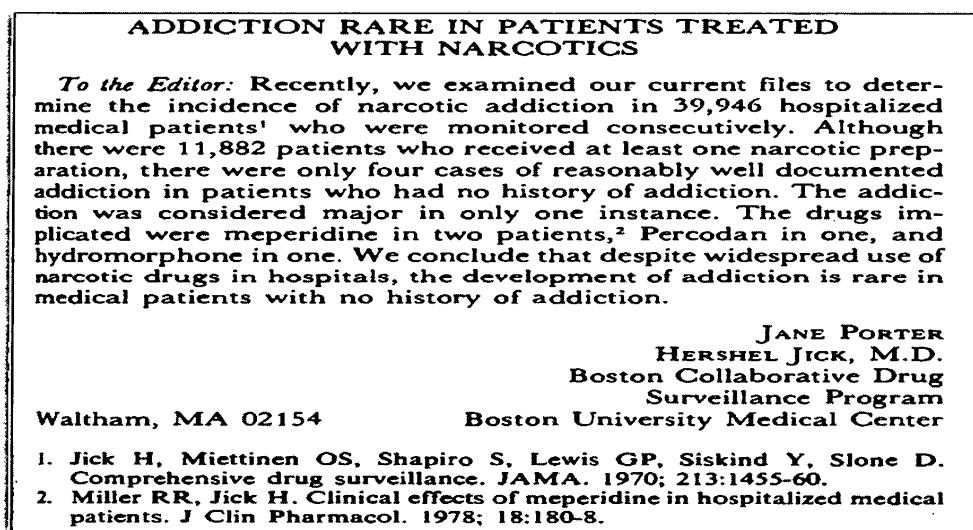
guidelines relating to opioids, including the AAPM's 2009 Guideline described above.

E. The Manufacturers' And KOLs' Marketing Campaign Is, And Always Has Been, Rooted In Scientifically Unsupported Conclusions.

117. Each of the Manufacturers and the KOLs made false and misleading statements about opioids. Each Manufacturer and KOL knew, or should have known, that such statements, as described herein, were false at the time they were made.

118. The medical community's understanding of opioids has not fundamentally changed in the past thirty years, and recent studies confirm that the Manufacturers' and the KOLs' statements about the risks and benefits of opioids are false.

119. For example, the Manufacturers and the KOLs cited a one-paragraph letter-to-the-editor published in the New England Journal of Medicine ("NEJM") in 1980 (hereafter, the "1980 NEJM Letter-to-the-Editor") that "conclude[d]...the development of addiction is rare in medical patients with no history of addiction."⁶³



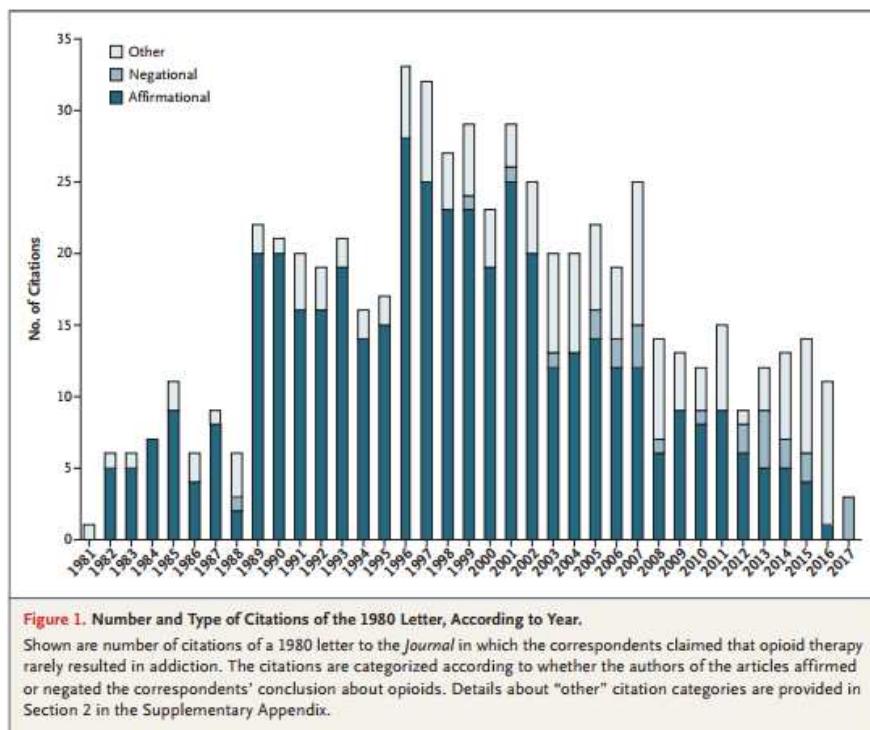
120. The study referenced in the 1980 NEJM Letter-to-the-Editor merely analyzed patients whom were not given long-term opioid prescriptions for use at home. Instead, they were

⁶³ Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N Engl J Med. 123 (Jan. 10, 1980), <http://www.nejm.org/doi/pdf/10.1056/NEJM19800110302021>.

prescribed opioids under in-patient doctor supervision at hospitals. The 1980 NEJM Letter-to-the-Editor also provided no evidence to support its conclusions.

121. The Manufacturers and the KOLs repeatedly cited the 1980 NEJM Letter-to-the-Editor to support their claim that patients treated with opioids rarely became addicted.⁶⁴

122. The 1980 NEJM Letter-to-the-Editor was cited at least 608 times.⁶⁵ The number of citations notably increased after OxyContin was introduced in 1995.⁶⁶



123. Of those 608 articles, 72.2% cited it “as evidence that addiction was rare in patients treated with opioids,” and 80.8% “did not note that the patients who were described in

⁶⁴ Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N Engl J Med. 123 (Jan. 10, 1980), <http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221>.

⁶⁵ Pamela T.M. Leung, et al., New England Journal of Medicine, *A 1980 Letter on the Risk of Opioid Addiction* (June 1, 2017), <http://www.nejm.org/doi/pdf/10.1056/NEJMc1700150>; see also Harrison Jacobs, Business Insider, *This one-paragraph letter may have launched the opioid epidemic* (May 26, 2016), <http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5>.

⁶⁶ Pamela T.M. Leung, et al., New England Journal of Medicine, *A 1980 Letter on the Risk of Opioid Addiction* (June 1, 2017), <http://www.nejm.org/doi/pdf/10.1056/NEJMc1700150> see also Harrison Jacobs, Business Insider, *This one-paragraph letter may have launched the opioid epidemic* (May 26, 2016), <http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5>.

the letter were hospitalized at the time they received the prescription.”⁶⁷

124. The misleading citation to the 1980 NEJM Letter-to-the-Editor became so pervasive that even Time magazine cited it as a “landmark study” and claimed it demonstrated that the “exaggerated fear that patients would become addicted [to opioids]...[was] basically unwarranted.”⁶⁸

125. The representations based on the 1980 NEJM Letter-to-the-Editor were false because the 1980 NEJM Letter-to-the-Editor “does not speak to the level of addiction in outpatients who take these drugs for chronic pain.”⁶⁹

126. Despite knowing the limited scope of the study, the Manufacturers’ and the KOLs’ misrepresentations based on this letter included claims that *less than one percent* of opioid users become addicted.⁷⁰

127. In 2017, the NEJM published a follow-up letter-to-the-editor in which it concluded that the misleading citations of the 1980 NEJM Letter-to-the-Editor “contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers’ concerns about the risk of addiction associated with long-term opioid therapy.”⁷¹

128. The Manufacturers and the KOLs contributed to the opioid epidemic by representing that the risk of addiction was low when opioids were prescribed to treat chronic pain. Defendant Dr. Russell Portenoy, a KOL, recently described the campaign of

⁶⁷ *Id.*

⁶⁸ Sam Allis Boston, Time, *Less Pain, More Gain* (June 24, 2001), <http://content.time.com/time/magazine/article/0,9171,158154,00.html>.

⁶⁹ Harrison Jacobs, Business Insider, *This one-paragraph letter may have launched the opioid epidemic* (May 26, 2016), <http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5>.

⁷⁰ See, e.g., Mike Mariani, The Week, “How the American opiate epidemic was started by one pharmaceutical company” (March 4, 2015), <http://theweek.com/articles/541564/how-american-opiate-epidemic-started-by-pharmaceutical-company> (“Through an array of promotional materials, including literature, brochures, videotapes, and Web content, Purdue proudly asserted that the potential for addiction was very small, at one point stating it to be ‘less than 1 percent.’”).

⁷¹ Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017), <http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article> (emphasis added).

misinformation:

I gave so many lectures to primary care audiences in which the [1980 NEJM letter] was just one piece of data that I would then cite – and I would then cite six, seven, maybe ten different avenues of thought, or avenues of evidence, none of which represented real evidence.

And yet, what I was trying to do, was to create a narrative so that the primary care audience would look at this information *in toto* and feel more comfortable about opioids, in a way they hadn't before. In essence, this was education to destigmatize, and because the primary goal was to destigmatize [opioids], we often left evidence behind.”⁷²

F. Each Of The Manufacturers And The KOLs Have Made, And Continue To Make, False Claims About Opioids.

129. Each Manufacturer and KOL knew, or should have known, that its statements about the low risk of addiction were false at the time they were made, and remain false today, as recent studies have confirmed. Each has failed to correct its false and misleading statements.

130. The Manufacturers and KOLs made material misrepresentations concerning the following subject matters, each of which is discussed in detail below: (1) the risk of addiction to opioids was low; (2) increased dosage of opioids should be used to treat pain; (3) there were effective strategies to reduce the risk of addiction and abuse; (4) higher dosages of opioids did not pose serious risks; (5) abuse-deterring technology existed to reduce the risks of abuse; and (6) patient functionality and quality of life improved through the long-term use of opioids.

1. The Manufacturers and KOLs misrepresented that the risk of opioid addiction was low.

131. The Manufacturers and KOLs have made false statements related to the risk of opioid addiction.

132. To expand the market for OxyContin, Purdue engaged in a campaign to

⁷² Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, <https://www.youtube.com/watch?v=DgyuBWN9D4w> (last visited October 11, 2017).

exaggerate the benefits of, and need for, OxyContin, while minimizing the known risks of OxyContin, including addiction, misuse, and diversion.

133. According to an internal Purdue document from 1990, drafted by Dr. Robert F. Kaiko, Purdue was aware before developing OxyContin that “in the State of Connecticut and perhaps other states, the substance abuse officials consider oxycodone combinations among the most abused Schedule II narcotic analgesic drugs.”⁷³ Dr. Kaiko noted oxycodone’s reputation as a “sleeping giant” among analgesics, “in that among all of the opioid analgesics utilized in fixed combinations, oxycodone is the only one with an analgesic potential comparable to that of morphine.”⁷⁴

134. Dr. Portenoy, the paid KOL described above, stated in a Purdue promotional video that “the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low.”⁷⁵

135. Dr. Alan Spanos, a pain specialist paid by Purdue,⁷⁶ purporting to rely on the 1980 NEJM Letter-to-the-Editor stated in a Purdue promotional video: “In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%*. They don’t wear out, they go on working, *they do not have serious medical side effects....*”⁷⁷ Purdue distributed this video to 15,000 doctors.⁷⁸

136. In reliance on the 1980 NEJM Letter-to-the-Editor, Purdue’s “Partners Against

⁷³ Robert F. Kaiko, Ph.D., Purdue Pharma Memo, *Controlled-Release Oxycodone* (July 16, 1990), <http://documents.latimes.com/purdue-need-new-painkiller-1990/>.

⁷⁴ *Id.*

⁷⁵ Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012), <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

⁷⁶ John Fauber and Ellen Gabler, Milwaukee Journal Sentinel and MedPage Today, *Anatomy of an Epidemic: The Opioid Movie* (Sept. 9, 2012), <https://www.medpagetoday.com/neurology/painmanagement/34650>.

⁷⁷ Our Amazing World, *Purdue Pharma OxyContin Commercial*, <https://www.youtube.com/watch?v=Er78Dj5hyeI> (last visited Sept. 7, 2017) (emphasis added).

⁷⁸ U.S. General Accounting Office, Report to Congressional Requesters, *OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), <http://www.gao.gov/new.items/d04110.pdf>.

Pain” website claimed that the addiction risk with OxyContin was very low.⁷⁹

137. Purdue misrepresented that there was no need to worry about addiction if taking opioids for legitimate, “medical” purposes:

Drug addiction means using a drug to get “high” rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.⁸⁰

138. With Purdue’s actual or constructive knowledge, and at Purdue’s direction, Purdue sales representatives misrepresented the low risk for addiction to doctors across the country.⁸¹ Purdue also marketed OxyContin for a wide variety of conditions and to doctors who were not adequately trained in pain management.⁸²

139. Endo also made misrepresentations about the low risk of addiction. For instance, it sponsored a website, PainKnowledge.com, on which it claimed that “[p]eople who take opioids as prescribed usually do not become addicted.”⁸³ The website has since been taken down. In another website, PainAction.com, still available online, Endo claimed that “most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.”⁸⁴

140. Endo began selling an opioid, oxymorphone, in 2005. That opioid, marketed under the brand name Opana, was chemically identical to a previous opioid, Numorphan. In 1974, a report by the National Institute of Drug Abuse entitled “Drugs and Addict Lifestyle,”

⁷⁹ Art Van Zee, M.D., *The OxyContin Abuse Problem: Spotlight on Purdue Pharma’s Marketing* (Aug. 22, 2001), <https://www.fda.gov/ohrms/dockets/dockets/01n0256/c000297-A.pdf>.

⁸⁰ Opioids.com, *The Marketing of Opioids* (accessed Oct. 20, 2017), <https://www.opioids.com/oxycodone/oxycontin.htm>.

⁸¹ Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, The New York Times (May 10, 2007), <http://www.nytimes.com/2007/05/10/business/11drug-web.html>.

⁸² U.S. General Accounting Office, Report to Congressional Requesters, *OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), <http://www.gao.gov/new.items/d04110.pdf>.

⁸³ German Lopez, *US officials are starting to treat opioid companies like Big Tobacco—and suing them*, Vox (Aug. 9, 2017), <https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits>.

⁸⁴ *Opioid medication and addiction*, Pain Action (Aug. 17, 2017), <https://www.painaction.com/opioid-medication-addiction/>.

revealed the popularity of Numorphan.⁸⁵ According to the report, Numorphan’s oral tablets were about twice as potent as morphine, and many addicts said they preferred the drug over heroin because it was “about 10 times more potent than morphine upon parenteral administration” [non-oral means of administration, including by injection].⁸⁶ In 1979, Endo agreed with the FDA to take Numorphan off the market following two decades of abuse by addicts.⁸⁷ Endo publically stated the removal was for “commercial reasons.”

141. Despite knowing the high potential for abuse inherent in oxymorphone, Endo sought FDA approval of Opana in 2003. During preliminary clinical trials of Opana, several patients overdosed on the drug and had to be revived with emergency doses of naloxone.⁸⁸ Endo promptly conducted new clinical trials using the concept of “enriched enrollment,” a clinical trial method that permitted Endo to remove anyone from the study who didn’t respond well to the drug.⁸⁹

142. The concept of “enriched enrollment” arose from the Initiative on Methods, Measurements, and Pain Assessment in Clinical Trials (“IMMPACT”).⁹⁰ Throughout the 2000s, IMMPACT hosted annual meetings where representatives of drug manufacturers – including Purdue, Endo, Janssen, Teva, and Actavis – could discuss clinical trial design with FDA officials.⁹¹ These meetings were by invitation only.⁹²

⁸⁵ Patricia Ferguson, et al., National Institute on Drug Abuse, *Drugs and Addict Lifestyle* at 238, <https://assets.documentcloud.org/documents/2074330/dalopana.pdf> (noting “widespread abuse of Numorphan as both a preference drug and as a drug to supplement other narcotics” and a belief that “tolerance to Numorphan builds very rapidly.”).

⁸⁶ *Id.* at 237.

⁸⁷ John Fauber, Milwaukee Journal Sentinel, *FDA seeks to remove a power opioid from the market for the second time* (June 9, 2017), <https://www.usatoday.com/story/news/2017/06/09/xxxxxx/384827001/>.

⁸⁸ John Fauber and Kristina Fiore, Milwaukee Journal Sentinel/MedPage Today, “A Look Back: Abandoned Painkiller Makes a Comeback” (June 9, 2017), <https://www.medpagetoday.com/psychiatry/addictions/65916>.

⁸⁹ *Id.*

⁹⁰ John Fauber and Kristina Fiore, Milwaukee Journal Sentinel, *Opana gets FDA approval despite history of abuse, limited effectiveness in trials* (May 9, 2015), <http://archive.jsonline.com/watchdog/watchdogreports/opana-gets-fda-approval-despite-history-of-abuse-limited-effectiveness-in-trials-b99494132z1-303198321.html>.

⁹¹ *Id.*

143. Relying on an “enriched enrollment” trial, the FDA approved Opana, even though the FDA acknowledged that “one could argue that the results [of the clinical trials with “enriched enrollment”] may not be generalizable to the wider chronic pain population.”⁹³

144. In June 2017, after twelve years on the market, the FDA expressed its “concern that the benefits of [Opana] may no longer outweigh the risks,” and asked Endo to remove Opana from the market.⁹⁴ The FDA based its decision “on a review of all available postmarketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product’s reformulation.”⁹⁵

145. Janssen currently states that concerns about opioid addiction are “overestimated” and that “true addiction occurs only in a small percentage of patients.”⁹⁶ Janssen also claimed that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.”⁹⁷

146. Upon information and belief, Actavis created sales training materials that contained misinformation about the risks and benefits of Kadian, particularly related to abuse and addiction. Upon information and belief, Actavis misrepresented that the risk of addiction was limited to chronic pain patients and/or patients already predisposed to abuse, addiction, and/or dysfunctional behavior. Upon information and belief, Actavis’ training materials specifically omitted information about the serious risks associated with high dose opioid therapy and/or long term opioid therapy. Upon information and belief, Actavis’ sales representatives

⁹² *Id.*

⁹³ *Id.*

⁹⁴ U.S. Food & Drug Administration, Press Release, *FDA requests removal of Opana ER for risks related to abuse* (June 8, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

⁹⁵ *Id.*

⁹⁶ Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last modified Jul. 2, 2015).

⁹⁷ German Lopez, *US officials are starting to treat opioid companies like Big Tobacco—and suing them*, Vox (Aug. 9, 2017), <https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits>.

then passed these misrepresentations on to physicians.

147. In addition, the Manufacturers used third parties and the Front Groups to advance their false and misleading statements about the safety of opioids. Dr. John D. Giglio, Executive Director of the APF, stated that “opioids are safe and effective, and only in rare cases lead to addiction.”⁹⁸ In a 2007 publication titled “Treatment Options: A Guide for People Living with Pain,” funded by Teva and Purdue, APF claimed: “Restricting access to the most effective medications for treating pain is not the solution to drug abuse or addiction.” APF also tried to normalize the dangers of opioids by listing opioids as one of several “[c]ommon drugs that can cause physical dependence,” including steroids, certain heart medications, and caffeine.

148. The statements made by the Manufacturers and the KOLs constituted misrepresentations and were false and misleading.

2. The Manufacturers and KOLs misrepresented that doctors should increase the dosage of opioids for patients that had symptoms of addiction.

149. The Manufacturers and KOLs also developed the false concept of “pseudoaddiction” and even reformulated the meaning of the word “addiction” altogether to convince doctors that their patients did not actually suffer from opioid addiction.

150. Dr. David Haddox – who later became a Senior Medical Director for Purdue – created the term “pseudoaddiction,” which he defined as “the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management.”⁹⁹ In other words, Dr. Haddox asserted that persons who presented with signs of addiction were not actually addicted to opioids, but, instead, merely suffered from improperly managed pain. Dr. Haddox

⁹⁸ *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions*, 107th Cong. 2 (Feb. 12, 2002) (testimony of John D. Giglio, M.A., J.D., Executive Director, American Pain Foundation), <https://www.help.senate.gov/imo/media/doc/Giglio.pdf>.

⁹⁹ David E. Weissman and J. David Haddox, *Opioid pseudoaddiction--an iatrogenic syndrome*, 36(3) Pain 363-66 (Mar. 1989), <https://www.ncbi.nlm.nih.gov/pubmed/2710565>.

recommended that such patients be prescribed more opioids.

151. The Manufacturers seized on Dr. Haddox's statements and used them as part of their marketing campaigns. The Front Groups, including APF and the Federation of State Medical Boards (another national group funded by the Manufacturers), repeated Dr. Haddox's claims in their literature.¹⁰⁰

152. APF also asserted that: "Physical dependence is normal; any patient who is taking an opioid on a regular basis for a few days should be assumed to be physically dependent. This does **NOT** mean you are addicted."¹⁰¹ APF advised that drug seeking behavior did not mean a patient was addicted, but only that the patient needed a larger dose because the patient's pain was more severe or the cause of the pain had changed:

Common drugs that can cause physical dependence <ul style="list-style-type: none"> ● Opioids ● Stimulants ● Sedatives ● Steroids ● Certain Antidepressants ● Certain Heart Medications ● Caffeine 	<p>Tolerance, physical dependence and addiction</p> <p>You and your healthcare provider may worry about tolerance, physical dependence and addiction. It's sometimes easy to confuse the meaning of these words. Tolerance refers to the situation in which a drug becomes less effective over time. However, many persons with persistent pain don't develop tolerance and stay on the same dose of opioid for a long time. Many times when a person needs a larger dose of a drug, it's because their pain is worse or the problem causing their pain has changed.</p> <p>Physical dependence means that a person will develop symptoms and signs of withdrawal (e.g., sweating, rapid heart rate, nausea, diarrhea, goosebumps, anxiety) if the drug is suddenly stopped or the dose is lowered too quickly. Physical dependence is normal; any patient who is taking an opioid on a regular basis for a few days should be assumed to be physically dependent. This does NOT mean you are addicted. In fact, many non-addictive drugs can produce physical dependence. To prevent withdrawal from occurring, the dose of the medication must be decreased slowly.</p> <p>If you believe that you no longer need to take the opioid medication or want to reduce the dose, it is essential to speak to your provider. They will guide you on how to decrease your dose over time to prevent the experience of withdrawal.</p>
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153. Purdue used Dr. Haddox's statements to encourage doctors to treat patients

¹⁰⁰ John Fauber, Milwaukee Journal Sentinel, *Painkiller boom fueled by networking*, <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/>.

¹⁰¹ *Treatment Options: A Guide for People Living with Pain*, American Pain Foundation, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last visited Sept. 7, 2017) (emphasis in original).

exhibiting signs of addiction by increasing their dosages of opioids, noting that “chronic pain has been historically undertreated.”¹⁰²

154. Purdue represented to doctors and patients that “[b]ehaviors that suggest drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior.”¹⁰³ Purdue’s statements were false and misleading.

155. Endo used the National Initiative on Pain Control (“NIPC”) – a program it controlled and funded – to promote the concept of pseudoaddiction and advised doctors that aberrant drug seeking behavior was the result of untreated pain.¹⁰⁴ In addition, a doctor affiliated with Janssen published a study claiming that “[m]any patients presenting to a doctor’s office asking for pain medications are accused of drug seeking. In reality, most of these patients may be undertreated for their pain syndrome.”¹⁰⁵

156. Janssen also promoted the concept of pseudoaddiction. A Janssen-sponsored website similarly stated that pseudoaddiction is different from true addiction “because such behaviors can be resolved with effective pain management.”¹⁰⁶ One of Janssen’s current websites, PrescribeResponsibly.com, defines pseudoaddiction as “a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed.

¹⁰² *Oxycontin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. On Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), <https://www.gpo.gov/fdsys/pkg/CHRG-107hrg75754/html/CHRG-107hrg75754.htm> (Noting that “surveys still show that half of the patients in this country with chronic pain are undertreated.”)

¹⁰³ *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P., <https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf> (last modified Nov. 2010).

¹⁰⁴ See, e.g., Wayback Machine, PainKnowledge.com (as of Feb. 10, 2004), <https://web.archive.org/web/20120119124921/http://www.painknowledge.org/aboutpain.aspx> (“Unfortunately, less than optimal training of physicians in pain disorders has led to the underassessment and undertreatment of patients who are living with pain.”).

¹⁰⁵ Howard A. Heit, MD, FACP, FASAM, *The truth about pain management: the difference between a pain patient and an addicted patient*, 5 European Journal of Pain 27-29 (2001), <http://www.med.uottawa.ca/courses/totalpain/pdf/doc-34.pdf>.

¹⁰⁶ Chris Morran, *Ohio: Makers Of OxyContin, Percocet & Other Opioids Helped Fuel Drug Epidemic By Misleading Doctors, Patients*, Consumerist (May 31, 2017), <https://consumerist.com/2017/05/31/ohio-makers-of-oxycontin-percocet-other-opioids-helped-fuel-drug-epidemic-by-misleading-doctors-patients/>.

Typically, when the pain is treated appropriately, the inappropriate behavior ceases.”¹⁰⁷

What a Prescriber Should Know Before Writing the First Prescription



TABLE 1: Definitions

8. **Pseudoaddiction** is a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate behavior ceases.²⁵

157. Upon information and belief, Actavis trained its sales representatives to emphasize the signs of “pseudoaddiction” to doctors.

158. The Manufacturers’ use of the concept of pseudoaddiction was not, and is not, supported by evidence. Even Dr. Portenoy recognized that “[t]he term [pseudoaddiction] has taken on a bit of a life of its own . . . That’s a mistake.”¹⁰⁸

3. The Manufacturers and KOLs misrepresented that addiction concerns could be minimized by risk-mitigation strategies, including tapering.

159. The Manufacturers and KOLs minimized the concerns regarding addiction by falsely asserting that addiction could be avoided and resolved through screening tools that

¹⁰⁷ Howard A. Heit, MD, FACP, FASAM and Douglas L. Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription, Prescribe Responsibly*, <http://www.prescriberresponsibly.com/articles/before-prescribing-opioids#pseudoaddiction> (last modified July 2, 2015).

¹⁰⁸ John Fauber, Milwaukee Journal Sentinel/MedPage Today, *Chronic Pain Fuels Boom in Opioids* (Feb. 19, 2012), <https://www.medpagetoday.com/neurology/painmanagement/31254>.

allowed doctors to identify risks and safely prescribe opioids to patients. In addition, the Manufacturers and KOLs advised doctors that tapering opioid doses would allow patients to safely cease opioid treatment.¹⁰⁹

160. Purdue advised doctors that patients should be screened to determine their potential to abuse or become addicted to opioids. Purdue represented that such screening would reduce incidences of addiction.¹¹⁰

161. Purdue currently represents to the public that certain patients have higher risk of opioid addiction because they have a history of substance abuse or mental illness. Purdue's representation downplays the risk of addiction for all patients and implies that it is the patients that are the cause of addiction and not opioids:¹¹¹

Assess each patient's risk for opioid addiction, abuse, or misuse prior to prescribing OxyContin, and monitor all patients receiving OxyContin for the development of these behaviors and conditions. Risks are increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depression). The potential for these risks should not, however, prevent the proper management of pain in any given patient. Patients at increased risk may be prescribed opioids such as OxyContin, but use in such patients necessitates intensive counseling about the risks and proper use of OxyContin along with intensive monitoring for signs of addiction, abuse, and misuse.

162. Purdue also claims that opioid dependence can be resolved easily by using a

¹⁰⁹ See, e.g., Joseph Rasor, PT, OMS IV, The Journal of the American Osteopathic Association, "Using Opioids for Patients With Moderate to Severe Pain," September 2007, Vol. 107, ES4-ES10, <http://jaoa.org/article.aspx?articleid=2093482> (CME publication, funded by Purdue, discussing a 12-week taper program); Bill H. McCarberg, MD, CME: Opioid Analgesia: Practical Treatment of the Patient With Chronic Pain (2003), <https://www.medscape.org/viewarticle/469428> (CME presentation, funded by Endo, instructing doctors to "start withdrawing the patient from the medication – tapering the dosage....once you start patients on medications, getting them off those drugs is hard...it is much easier when you have done it that way.").

¹¹⁰ *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P., <https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf> (last modified Nov. 2010).

¹¹¹ OxyContin, <https://www.oxycontin.com/index.html> (last visited Sept. 7, 2017).

tapering schedule when stopping opioid treatment.¹¹² Purdue instructed doctors to taper someone off of OxyContin to prevent problems associated with withdrawal in patients who were physically dependent on opioids.¹¹³ Purdue did not warn doctors or patients that tapering may be inadequate to safely end opioid treatment.

163. Endo represented that assessment tools can assess risks for addiction and even “[t]he potential for these risks should not, however, prevent proper management of pain in any given patient.”¹¹⁴ Before taking down its website for Opana, Endo also instructed doctors and patients that “[w]hen discontinuing OPANA ER, gradually taper the dosage.”¹¹⁵

164. Janssen likewise represents to doctors and the general public that opioid addiction “can usually be managed” and that written agreements between a doctor and patient that facilitate informed consent can reduce the risk of addiction and misuse of opioids.¹¹⁶

165. Upon information and belief, Actavis misrepresented via its sales representatives that the physical symptoms of opioid withdrawal could be adequately addressed by tapering.

166. The Manufacturers’ and KOLs’ representations were false. There are no reliable screening tests or questions to determine whether someone has the propensity to become addicted. Anyone can become addicted to opioids, even when using them as prescribed by a physician.¹¹⁷

¹¹² OxyContin, <https://www.oxycontin.com/index.html> (last visited Sept. 7, 2017); *OxyContin Full Prescribing Information*, Purdue Pharma LP, <http://app.purduepharma.com/xmlpublishing/pi.aspx?id=0> (last visited Sept. 7, 2017).

¹¹³ Purdue Pharma, *Dear Healthcare Professional* (Oct. 4, 2010), <http://webcache.googleusercontent.com/search?q=cache:Yhi3TrVHeGIJ:www.purduepharma.com/pdfs/DearHCPLetter.pdf+&cd=1&hl=en&ct=clnk&gl=us> (last visited Nov. 29, 2017).

¹¹⁴ Opana ER, <http://www.opana.com> (last visited Sept. 7, 2017).

¹¹⁵ *Id.*

¹¹⁶ Prescribe Responsibly, “What a Prescriber Should Know Before Writing the First Prescription” (last modified July 2, 2015), <https://www.prescriberesponsibly.com/articles/before-prescribing-opioids>.

¹¹⁷ Walter Ling, et al., “Prescription opioid abuse, pain and addiction: Clinical issues and implications,” *Drug Alcohol Rev.* 2011 May ; 30(3): 300–305, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4170948/pdf/nihms617787.pdf> (“Pain may contribute to the

167. Each Manufacturer’s and KOL’s statements about tapering misrepresented that gradual tapering would be sufficient to alleviate any risk of withdrawal or addiction while taking opioids.

4. The Manufacturers and the KOLs misrepresented that doctors and patients could increase opioid dosage indefinitely without added risk and failed to disclose the risks associated with higher dosages.

168. The Manufacturers and the KOLs, directly or through Front Groups, made false and misleading statements regarding dosage that have contributed to the opioid epidemic.

169. In 2012, APF claimed on its website that there was no “ceiling dose” for opioids for chronic pain.¹¹⁸ APF also made this claim in a guide sponsored by Purdue, which is still available online.

170. A Purdue regional manager instructed that representatives should “convinc[e] the physician that there is no need” for prescribing OxyContin in shorter intervals than the recommended 12-hour interval and, instead, the solution is prescribing higher doses. The manager directed representatives to discuss with physicians that there is “no[] upward limit” for dosing and to ask “if there are any reservations in using a dose of 240mg-320mg of OxyContin.”¹¹⁹

171. Teva promoted Actiq for use in non-cancer patients to treat such conditions as migraines, sickle-cell pain crises, and other injuries.¹²⁰ Teva also made statements promoting Actiq for use in patients who were not yet opioid-tolerant, and targeted such statements towards

development of opioid abuse and addiction, which may emerge after a period of legitimate use of opioids as prescribed for analgesia.”).

¹¹⁸ Noah Nesin, M.D., FAAFP, *Responsible Opioid Prescribing*, PCHC https://www.mainequalitycounts.org/image_upload/Keynote-%20Managing%20Chronic%20Pain%20and%20Opioids_Nesin.pdf (last visited Sept. 7, 2017).

¹¹⁹ *Sales manager on 12-hour dosing*, Los Angeles Times (May 5, 2016), <http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/>.

¹²⁰ United States Department of Justice, “Pharmaceutical Company Cephalon To Pay \$425 Million For Off-Label Drug Marketing” (Sept. 29, 2008), <https://www.justice.gov/sites/default/files/civil/legacy/2014/01/09/Cephalon%20Press%20Release.pdf>.

physicians other than oncologists, including general practitioners.¹²¹ In so doing, Teva knowingly targeted patients for whom Actiq could have life-threatening results.¹²²

172. The FDA warned Teva about its online marketing, finding that company-sponsored links on Internet search engines such as Google misrepresented the efficacy of Fentora without communicating any risk information.¹²³

173. Upon information and belief, Endo published a patient handout that assured patients that “[j]ust because you are tolerant and need more medication does not mean that you are addicted.”¹²⁴ The website on which Endo made this misrepresentation, PainKnowledge.com, described itself as “a one-stop repository for print materials, educational resources, and physician tools across the broad spectrum of pain assessment, treatment, and management approaches,” but failed to disclose its association with Endo.¹²⁵ Dr. Perry Fine was on the website’s “Steering Committee.”¹²⁶ PainKnowledge.com is no longer an active website.¹²⁷

174. In a publication titled “Understanding Your Pain: Taking Oral Opioid Analgesics,” Endo assures opioid users that concern about developing tolerance to the drugs’ pain-relieving effect is “not a problem,” and that “[t]he dose can be increased” and “[y]ou won’t ‘run out’ of pain relief.”¹²⁸

175. Janssen discussed the disadvantages of dosage limits for pain medicines in a 2009

¹²¹ *Id.*

¹²² *Id.*

¹²³ Lynne Taylor, Pharma Times, “Big Pharma firms warned over Internet drug ads” (April 7, 2009), http://www.pharmatimes.com/news/big_pharma_firms_warned_over_internet_drug_ads_985134.

¹²⁴ See Wayback Machine, PainKnowledge.com PAIN Opioid Therapy Patient Handout, https://web.archive.org/web/20101007083722/http://painlessknowledge.org/patient/pdf/B697_%20Patient%20Handout_FINAL.pdf

¹²⁵ See Wayback Machine, About PainKnowledge.com, <https://web.archive.org/web/20120119124921/http://www.painlessknowledge.org/aboutpainless.aspx>.

¹²⁶ See Wayback Machine, Steering Committee, <https://web.archive.org/web/20120119103221/http://www.painlessknowledge.org/faculty/pk/faculty.aspx>.

¹²⁷ <http://painlessknowledge.com/>.

¹²⁸ *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004), http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.

patient education guide, but failed to address the risks of dosage increases.¹²⁹

176. Upon information and belief, Actavis' training materials specifically omitted information about the serious risks associated with high dose opioid therapy and/or long term opioid therapy. Upon information and belief, Actavis' paid physician speakers in turn made misrepresentations about addiction risk profiles to other prescribing physicians and omitted information about the serious risks associated with high dose opioid therapy and/or long term opioid therapy.

177. The FDA sent Actavis a "Warning Letter" regarding Actavis' promotion of Kadian.¹³⁰ The FDA identified two documents, a "Co-Pay Assistance Program" brochure for Kadian and a "PK to PK Comparison Detailer for Kadian", and determined they "[were] false or misleading because they omit and minimize the serious risks associated with the drug, broaden and fail to present the limitations to the approved indication of the drug, and present unsubstantiated superiority and effectiveness claims."¹³¹ The FDA warned Actavis against distributing further promotional materials that "minimize[] the risks associated with Kadian and misleadingly suggest[] that Kadian is safer than has been demonstrated," because such promotional materials "fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed."¹³²

¹²⁹ See Vasudevan, Sridhar V. *Multidisciplinary Management of Chronic Pain: a Practical Guide for Clinicians*, Springer, 2015, p. 77, <https://books.google.com/books?id=AFh1CgAAQBAJ&pg=PA77&lpg=PA77&dq=2009+%22Finding+Relief:+Pain+Management+for+Older+Adults%22&source=bl&ots=DqFa-RL1OE&sig=bsMgaPXrX1ZVdC6sK4GdhtBjB-Q&hl=en&sa=X&ved=0ahUKEwjatdyAivPXAhVs34MKHXLTBLoQ6AEIOjAD#v=onepage&q=2009%20%22Finding%20Relief%3A%20Pain%20Management%20for%20Older%20Adults%22&f=false>.

¹³⁰ Warning Letter from Thomas Abrams, Director Division of Drug Marketing, Advertising and Communications, U.S. Food and Drug Administration, to Doug Boothe, Chief Executive Officer, Actavis US (Feb. 18, 2010), <https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf>.

¹³¹ *Id.*

¹³² *Id.*

5. The Manufacturers misrepresented that reformulated opioids can curb addiction and abuse.

178. The Manufacturers have made, and continue to make, misrepresentations about the purported abuse-deterrent properties of reformulated pills.

179. Purdue misrepresented that “abuse resistant products can reduce the incidence of abuse.”¹³³ Its current website claims abuse-deterrent properties “can make a difference.”¹³⁴

180. On August 17, 2015, Purdue announced the launch of a new website, “Team Against Opioid Abuse,” which it said was “designed to help healthcare professionals and laypeople alike learn about different abuse-deterrent technologies and how they can help in the reduction of misuse and abuse of opioids.”¹³⁵ This website appears to no longer be active.

181. A study, whose authors included doctors formerly working for Purdue, stated that “[a]buse-deterrent formulations of opioid analgesics can reduce abuse.”¹³⁶ A 2016 study, which includes at least one doctor affiliated with Purdue as an author, claims that abuse decreased by as much as 99% in some situations after abuse-deterrent formulations were introduced.¹³⁷

182. Endo changed its formula for Opana ER to one with purported abuse-deterrent properties. Although the FDA determined the data did not back up Endo’s claims that the new formula could reduce abuse, Endo advertised its reformulated pills as “crush resistant” and directed its sales representatives to state the same. Endo agreed with the Attorney General of the

¹³³ Art Van Zee, M.D., *The OxyContin Abuse Problem: Spotlight on Purdue Pharma’s Marketing* (Aug. 22, 2001), <https://www.fda.gov/ohrms/dockets/dockets/01n0256/c000297-A.pdf>.

¹³⁴ *Opioids with Abuse-Deterrent Properties*, Purdue, <http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/> (last visited Sept. 7, 2017).

¹³⁵ *Purdue Pharma L.P. Launches TeamAgainstOpioidAbuse.com*, Purdue (Aug. 17, 2015), <http://www.purduepharma.com/news-media/2015/08/purdue-pharma-l-p-launches-teamagainstopioidabuse-com/>.

¹³⁶ Paul M. Coplan, Hrishikesh Kale, Lauren Sandstrom, Craig Landau, and Howard D. Chilcoat, *Changes in oxycodone and heroin exposures in the National Poison Data System after introduction of extended-release oxycodone with abuse-deterrent characteristics*, 22 (12) *Pharmacoepidemiol Drug Saf.* 1274-82 (Sept. 30, 2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4283730/>.

¹³⁷ Paul M. Coplan, Howard D. Chilcoat, Stephen Butler, Edward M. Sellers, Aditi Kadakia, Venkatesh Harikrishnan, J. David Haddox, and Richard C. Dart, *The effect of an abuse-deterrent opioid formulation (OxyContin) on opioid abuse-related outcomes in the postmarketing setting*, 100 *Clin. Pharmacol. Ther.*, 275-86 (June 22, 2016), <http://onlinelibrary.wiley.com/doi/10.1002/cpt.390/full>.

State of New York that it would discontinue making such statements.¹³⁸

6. The Manufacturers misrepresented that opioid use improved patients' function and quality of life.

183. The Manufacturers misrepresented that there was a significant upside to long-term opioid use, including restoration or improvement of function and quality of life.

184. Purdue sponsored the development and distribution of a 2011 APF guide which claimed that “multiple clinical studies have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients.” This guide is still available today.

185. Upon information and belief, Purdue and Endo paid for, at least in part, and disseminated Dr. Webster’s book, *Avoiding Opioid Abuse While Managing Pain*, that claims opioids improved patients’ function. The book remains for sale online today.

186. Endo’s advertisements suggested Opana ER allowed patients to engage in construction. Its Opana ER ads depicted Opana ER users as healthy and unimpaired.

187. Endo’s NIPC website claimed that by taking opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.”

188. Endo sponsored CMEs through NIPC that claimed chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.”

189. Endo helped publish guidelines stating that “Opioid Medications are a powerful and often highly effective tool in treating pain,” and “they can help restore comfort, function, and

¹³⁸ Press Release, Attorney General Eric T. Schneiderman, *A.G. Schneiderman Announces Settlement with Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing of Prescription Opioid Drugs* (Mar. 3, 2016), <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals>.

quality of life.”¹³⁹

190. Teva and Purdue funded an APP publication entitled “Treatment Options: A Guide for People Living with Pain,” which represented to pain patients that, when used properly, opioids “can be life savers and give all of us a quality of life we deserve.”¹⁴⁰ This publication is still available online.¹⁴¹

191. Janssen assisted in publishing patient guides in which it stated that “opioids may make it easier for people to live normally,” including sleeping through the night, returning to work, recreation, sex, walking and climbing stairs.

192. Upon information and belief, Janssen assisted with a website which claimed opioids allowed a patient to “continue to function.”

193. Upon information and belief, Actavis trained its sales representatives to misrepresent that opioids would improve patients’ function.

194. The Manufacturers’ sales representatives communicated, and continue to communicate, the message that opioids will improve patients’ function, without appropriate disclaimers.

G. The Manufacturers And KOLs Made False And Misleading Statements To Persons, Including Physicians, In Columbus.

195. Upon information and belief, the Manufacturers and KOLs made each of the specific misrepresentations set forth Section II.F, above, to persons and physicians in Columbus and the surrounding areas. As a result, persons in Columbus and the surrounding areas were prescribed significant amounts of opioids.

196. Upon information and belief, Manufacturers sent sales representatives to

¹³⁹ *Informed Consent for Using Opioids to Treat Pain*, Painknowledge.org (2007), https://www.mainequalitycounts.org/image_upload/Opioid%20Informed%20Consent%20Formatted_1_23_2008.pdf

¹⁴⁰ American Pain Foundation, “Treatment Options: A Guide for People Living with Pain,” <https://assets.documentcloud.org/documents/277605/afp-treatmentoptions.pdf>.

¹⁴¹ *Id.*

Columbus and its surrounding areas to tout the asserted benefits and low risks of opioid use to treat chronic pain. The Manufacturers and KOLS knew or should have known that doctors in Columbus and the surrounding areas would rely on the Manufacturers' and KOLs' statements and prescribe opioids to treat chronic pain.

197. In addition, the Manufacturers and KOLs have made, and continue to make, payments to doctors in Columbus for marketing these drugs. For example, according to publicly available records, Purdue paid at least one Columbus doctor over \$30,000 in consulting and promotional speaking fees between August 2013 and December 2015 relating to Butrans, Hysingla ER, and OxyContin.¹⁴²

III. THE MANUFACTURERS' AND KOLS' STATEMENTS ABOUT THE RISKS AND BENEFITS OF OPIOIDS WERE, AND ARE, FALSE.

198. The CDC issued its *CDC Guideline for Prescribing Opioids for Chronic Pain* on March 15, 2016 (the “2016 CDC Guideline” or “Guideline”).¹⁴³ The recommendations in the 2016 CDC Guideline were further made “on the basis of a systematic review of the best available evidence.”¹⁴⁴ The findings in the 2016 CDC Guideline confirmed scientific evidence regarding the questionable efficacy of opioid use.

199. The 2016 CDC Guideline confirmed that “[e]xtensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury)” and that “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder.”¹⁴⁵ The Guideline further confirms the existence of opioid withdrawal.

200. The 2016 CDC Guideline states that there is “[n]o evidence” to show “a long-

¹⁴² ProPublica, Dollars for Docs, Gladstone C. McDowell, <https://projects.propublica.org/docdollars/doctors/pid/242959>.

¹⁴³ Deborah Dowell, Tamara M. Haegerich, and Roger Chou, Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016* (March 15, 2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

term benefit of opioids in pain and function versus no opioids for chronic pain . . .” The Guideline also states that “continuing opioid therapy for 3 months substantially increases the risk of opioid use disorder.”¹⁴⁶ The Guideline further indicates that “[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,” and that physicians should “reassess[] pain and function within 1 month” to decide whether to “minimize risks of long-term opioid use by discontinuing opioids.”¹⁴⁷

201. The 2016 CDC Guideline finds that “[a]lthough opioids can reduce pain during short-term use, *the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.*”¹⁴⁸ The CDC further finds that “evidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.”¹⁴⁹

202. The 2016 CDC Guideline finds that “[b]enefits of high-dose opioids for chronic pain are not established” while the “risks for serious harms related to opioid therapy increase at higher opioid dosage.”¹⁵⁰ The CDC also finds that there is an “increased risk[] for opioid use disorder, respiratory depression, and death at higher dosages.”¹⁵¹ The CDC advised doctors to “avoid increasing dosage” above 90 morphine milligram equivalents per day.¹⁵²

203. The 2016 CDC Guideline indicates that available risk screening tools “show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ *Id.* (emphasis added).

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.*

misuse” and counsels that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.”¹⁵³

204. The 2016 CDC Guideline additionally states that “[n]o studies” support the notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse.” The CDC found such technologies “do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes.”¹⁵⁴

IV. BY FAILING TO REPORT SUSPICIOUS SHIPMENTS, THE MANUFACTURERS AND DISTRIBUTORS CAUSED THE OPIOID EPIDEMIC.

A. The Manufacturers And Distributors Have A Legal Duty to Prevent “Suspicious Orders” of Opioids.

205. In 1970, Congress devised a “closed” chain of distribution specifically designed to prevent legally produced controlled substances from being diverted into the illegal market. *Gonzales v. Raich*, 525 U.S. 1, 12-14 (2005); 21 U.S.C. §§ 801(2), 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970). The term “controlled substance” means “a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V” of the Controlled Substances Act, as discussed above. 21 U.S.C. § 801(6).

206. Federal law mandates that Manufacturers and the Distributors “shall inform the Field Division Office of the Administration in his area of suspicious orders [of controlled substances] when discovered by the registrant [Manufacturers and Distributors]. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b). Thus, under this closed system, the Manufacturers and Distributors have the duty to monitor, identify, halt, and report “suspicious orders” of controlled substances. *Masters Pharm., Inc. v. Drug Enf’t Admin.*, 861 F.3d 206

¹⁵³ *Id.*

¹⁵⁴ *Id.*

(D.C. Cir. 2017).

207. “Suspicious orders” are not determined by any one test. An order that deviates substantially from a normal pattern – no matter the size of the order – must be reported as suspicious. Deviation from normal patterns relates to patterns of ordering from particular customers, from the entirety of the wholesale distributor’s customer base or the relevant segment of the wholesale distributor industry. Deviation from a pattern is not the sole factor to consider in determining whether an order is suspicious. The size of an order is enough to trigger the wholesale distributor’s responsibility to report the order as suspicious. *Masters Pharm., Inc.*, at 215 (“DEA regulations expressly provide that deviations in size, frequency, *or* pattern are the sort of indicia that give rise to a suspicion and, unless the suspicion is dispelled, the obligation to report.”) (emphasis added).

208. Federal law requires that Manufacturers and Distributors maintain “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” *See* 21 U.S.C. §§ 823(a) (1), 823(b)(1). Each Manufacturer and Distributor was required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823; 21 C.F.R. § 1301.11(a) (“Every person who manufactures, distributes, imports, or exports any controlled substances...shall obtain a registration”).

209. Ohio incorporates the above described federal requirements through statutes and regulations promulgated by the Ohio Board of Pharmacy, which mandate that “[w]holesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.” O.A.C. § 4729-9-16(L); *see also* § 4729-9-28(I); O.R.C. § 4729.26 (“The state board of pharmacy may adopt rules in accordance with Chapter 119 of the Revised Code, not inconsistent with the law, as may be necessary to carry out the purposes of and to enforce the

provisions of this chapter.”). Ohio requires the Manufacturers and Distributors to “establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs,” and that, as a minimum requirement of wholesale distribution in this State, “[a] system shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse.” O.A.C. § 4729-9-16(H).

210. Ohio requires the Manufacturers and Distributors to “first obtain a license as a wholesaler of controlled substances from the state board of pharmacy.” O.R.C. § 3719.021. Each Manufacturer and Distributor is licensed by the Ohio Board of Pharmacy and is a “registrant” as a wholesale distributor in the chain of distribution of Schedule II controlled substances and assumes a duty to comply with all requirements imposed by the Board of Pharmacy.

211. Ohio independently requires the Manufacturers and Distributors to report “suspicious orders” to the Ohio Board of Pharmacy:

The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs when discovered. Suspicious orders are those which, in relation to the wholesaler’s records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns.

Reports generated by the system shall be furnished to the state board of pharmacy within three working days of receipt of a request from the board. The reports shall include the name and address of the purchaser, date of purchases, product trade name, national drug code (NDC) number, size of package, and quantity purchased.

O.A.C. § 4729-9-16(H)(1)(e); *see also* 4729-9-12(G); 4729-9-28(E).

212. In addition to federal and Ohio law, industry compliance guidelines from the Healthcare Distribution Management Association (now known as the Healthcare Distribution Alliance) further indicate that the Manufacturers and Distributors, as the entities “[a]t the center

of a sophisticated supply chain,” must monitor, detect, report and refuse to fill suspicious orders. The Healthcare Distribution Management Association advised that distributors should perform due diligence and create monitoring systems to ensure that they do not ship suspicious orders referred to as “orders of interest.”¹⁵⁵

213. In sum, the Manufacturers and Distributors are “key components of the distribution chain. If the closed system is to function properly … distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as … the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.”¹⁵⁶

214. The Manufacturers and the Distributors are a major line of defense to prevent the excessive sales of legal pharmaceutical controlled substances. Therefore, federal and Ohio law mandate that the Manufacturers and the Distributors maintain effective controls to prevent oversaturation of opioids. Should a Manufacturer or Distributor deviate from these checks and balances, the closed system collapses.¹⁵⁷

B. The Manufacturers And The Distributors Intentionally And/Or Recklessly Breached Their Duties.

215. The DEA repeatedly has taken administrative action to force compliance. The United States Department of Justice, Office of the Inspector General, Evaluation and Inspections

¹⁵⁵ “Prescribing Drug Diversion: Combating the Scourge” (March 1, 2012), https://archive.org/stream/gov.gpo.fdsys.CHRG-112hrg80861/CHRG-112hrg80861_djvu.txt.

¹⁵⁶ See U.S. Department of Justice, Drug Enforcement Administration, letter to Cardinal Health dated September 27, 2006 (“This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.”) (a copy of letter is filed at *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-51 (filed therein in D.D.C. on February 20, 2012)).

¹⁵⁷ See Declaration of Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Agency, United States Department of Justice, ¶ 10, *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW, Doc. 14-2 (filed in D.D.C. on February 20, 2012).

Division, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.¹⁵⁸

216. Defendants Cardinal Health and McKesson were fined millions of dollars and issued Orders to Show Cause by the DEA for failing to maintain effective controls to prevent the diversion of controlled substances for illicit purposes. In addition, Defendant AmerisourceBergen was the subject of a criminal investigation concerning “its oversight of painkiller sales” in 2012. AmerisourceBergen settled with the state of West Virginia on January 10, 2017 for \$16 million.¹⁵⁹

217. In response to the fines, lawsuits and Orders to Show Cause, the Distributors purported to create greater controls to identify and prevent the shipment of suspicious orders of Opioids.

218. For example, Cardinal Health claims that it uses “advanced analytics” to monitor its supply chain, and assured the public it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”¹⁶⁰ Similarly, McKesson claims that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders,” and is “deeply passionate about curbing the opioid epidemic in our

¹⁵⁸The Drug Enforcement Administration’s Adjudication of Registrant Actions, United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I-2014-003 (May 2014), available at <https://oig.justice.gov/reports/2014/e1403.pdf>.

¹⁵⁹Kyla Asbury, West Virginia Record, “Cardinal Health, AmerisourceBergen settle pain pill lawsuit for \$36 million” (Jan. 10, 2017), <https://wvrecord.com/stories/511071502-cardinal-health-amerisourcebergen-settle-pain-pill-lawsuit-for-36-million>.

¹⁶⁰Lenny Bernstein et al., *How drugs intended for patients ended up in the hands of illegal users: ‘No one was doing their job’*, The Washington Post(October 22, 2016), available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8fff-7b6c1998b7a0_story.html?utm_term=.744e85035bdc.

country.”¹⁶¹ AmerisourceBergen also claims to use “a sophisticated set of algorithms and data analytics” and recently announced its continued investment in a “best-in-class Diversion Control Team, comprised of internal and external experts including former law enforcement professionals, diversion investigators, pharmacists, and pharmacy technicians that maintains an ongoing order monitoring program, conducts customer site visits, participates in surveillance activities, reviews customer policies and identifies and reports suspicious orders.”¹⁶²

219. Despite the Distributors’ claims about their monitoring and detection capabilities, opioids have flooded Columbus in such numbers that either the controls are illusory and the Distributors intentionally ignored suspicious orders, or, the Distributors negligently shipped suspicious orders.

220. Upon information and belief, the volume of opioids distributed into Columbus and the surrounding area exceeded the medical need of the community and the Distributors should have known they were filling suspicious orders.

221. Based on this volume, upon information and belief, the Manufacturers and Distributors unlawfully filled and failed to report suspicious orders of opioids that were delivered and/or diverted into Columbus and its surrounding areas.

222. Each Manufacturer and Distributor breached its duties to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids headed to Columbus and its surrounding areas.

223. The Manufacturers’ and the Distributors’ continued and repeated shipments of

¹⁶¹ Scott Higham *et al.*, *Drug industry hired dozens of officials from the DEA as the agency tried to curb opioid abuse*, The Washington Post (December 22, 2016), available at https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.68a58d17478e.

¹⁶² “AmerisourceBergen Announces Operating Commitments to Address Opioid Diversion and Abuse” (Dec. 7, 2017), <https://www.businesswire.com/news/home/20171207005566/en/>.

suspicious orders was wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

C. The Manufacturers And Distributors Spent Millions Of Dollars Lobbying Congress To Weaken DEA Enforcement Efforts Against Them.

224. While the Manufacturers and Defendants publicly stated that they had increased their efforts to detect, monitor and prevent suspicious orders, the Manufacturers and Distributors also developed another strategy to prevent fines and investigation by the DEA – spend millions of dollars lobbying Congress to weaken the DEA’s ability to enforce federal regulations against the Manufacturers and Defendants.

225. Upon information and belief, the Manufacturers and the Distributors have spent the past decade lobbying Congress to decrease the number of immediate suspension orders issued by the DEA.¹⁶³ An immediate suspension order is a DEA tool used to freeze a distributor from distributing drugs.

226. Overall, the drug industry, including the Manufacturers and the Distributors, spent \$102 million lobbying Congress on the Effective Drug Enforcement Act and other legislation between 2014 and 2016.¹⁶⁴

227. The Manufacturers’ and the Distributors’ lobbying efforts to minimize immediate suspension orders has been successful: the DEA issued 65 such orders in 2011, and that number

¹⁶³ Scott Higham and Lenny Bernstein, The Washington Post, *The Drug Industry’s Triumph Over The DEA* (Oct. 15, 2017), available at: https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.37b4a0d6ae33; Lenny Bernstein and Scott Higham, The Washington Post, *Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control* (October 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.7ba890887d7b; Lenny Bernstein and Scott Higham, The Washington Post, *Investigation: U.S. senator calls for investigation of DEA enforcement slowdown amid opioid crisis* (March 6, 2017), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.83d382cede93; Eric Eyre, Charleston Gazette, *DEA agent: ‘We had no leadership’ in WV amid flood of pain pills* (February 18, 2017), <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills->.

¹⁶⁴Id.

dropped to only 6 throughout the first ten months of 2017.¹⁶⁵

DECLINING SUSPENSION ORDERS

The number of **immediate suspension orders** against doctors, pharmacies and drug companies has plummeted since fiscal year 2011.



Source: Drug Enforcement Administration

228. Not a single immediate suspension order has targeted a distributor or manufacturer of opioids since late 2015.

229. The Manufacturers' and the Distributors' lobbying efforts led to, among other things, the Ensuring Patient Access and Effective Drug Enforcement Act (the "Effective Drug Enforcement Act"), PL 114-145, April 19, 2016, 130 Stat. 354, passed by Congress in 2016.

230. Despite the DEA's resistance to the Effective Drug Enforcement Act, Congress passed the bill unanimously.¹⁶⁶ One DEA official is quoted as noting that Congress "would have passed [the bill] with us or without us . . . Our point was that this law was completely unnecessary."¹⁶⁷

231. According to DEA Chief Administrative Law Judge John J. Mulrooney II, the bill does not live up to its name. In a draft 115-page article pending publication by the Marquette Law Review, ALJ Mulrooney wrote that, "[a]t a time when, by all accounts, opioid abuse,

¹⁶⁵*Id.*

¹⁶⁶*Id.*

¹⁶⁷*Id.*

addiction and deaths were increasing markedly ... [the new law] imposed a dramatic diminution of the [DEA's] authority.”¹⁶⁸ ALJ Mulrooney noted it was now “all but logically impossible” for the DEA to suspend a drug company’s operations for failing to comply with federal law.¹⁶⁹ ALJ Mulrooney further stated: “[i]f it had been the intent of Congress to completely eliminate the DEA’s ability to ever impose an immediate suspension on distributors or manufacturers, it would be difficult to conceive of a more effective vehicle for achieving that goal.”¹⁷⁰

V. THE MANUFACTURERS’, DISTRIBUTORS’ AND KOLS’ ACTIONS CAUSED AN ILLICIT OPIOID EPIDEMIC IN COLUMBUS.

232. As a direct result of opioid abuse, individuals who have become addicted to opioids – but cannot afford their increased costs or are unable to secure a prescription – have turned to cheaper, more potent, and dangerous alternatives, including heroin and fentanyl, fueling a related epidemic directly attributable to prescription opioid abuse.

233. Columbus is the largest city in the state of Ohio. It also is the largest city in the five-state region of Indiana, Michigan, Ohio, Kentucky, and West Virginia, and the fifth-largest city in the United States east of the Mississippi River.¹⁷¹

234. Columbus is located at the center of the most densely populated area of the United States: approximately 45 percent of the United States population lives within a ten hour drive of Columbus, more than any other city in the country.¹⁷²

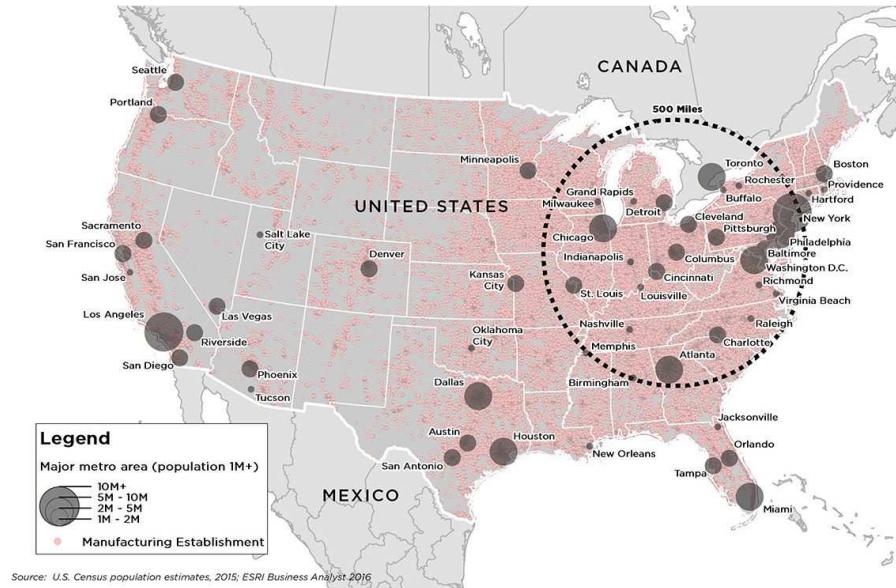
¹⁶⁸ John J. Mulrooney II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 MARQ. L. REV. (forthcoming Feb. 2018).

¹⁶⁹ Scott Higham and Lenny Bernstein, The Washington Post, *The Drug Industry’s Triumph Over The DEA* (Oct. 15, 2017), available at: https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.37b4a0d6ae33.

¹⁷⁰*Id.*

¹⁷¹ United States Census Bureau, “The 15 Most Populous Cities: July 1, 2016” (July 1, 2016), <https://www.census.gov/content/dam/Census/newsroom/releases/2017/cb17-81-table3-most-populous.pdf>.

¹⁷² Columbus 2020, “The Region with Reach,” <http://columbusregion.com/doing-business/transportation-infrastructure/> (accessed on October 18, 2017).



235. By the early 2000s, Columbus had become a major crossroad in America's opioid epidemic, as the Manufacturers', the Distributors' and the KOLs' efforts to increase the number of opioid prescriptions, and failures to properly monitor shipments, intersected with Columbus' size, location and distribution channels.¹⁷³

236. At the same time as the Manufacturers, Distributors and KOLs were marketing and distributing opioids throughout Columbus, illicit drug dealers in Columbus identified a significant opportunity, and began offering persons addicted to prescription opioids black tar heroin – a less expensive product with the same (or even stronger) narcotic effect – in an attempt to recruit more customers.

237. Black tar heroin is a semi-processed form of heroin – heroin acetate – that primarily came to Columbus from the Pacific coast of Mexico. It can be injected or smoked, and it offers the user an inexpensive, potent opioid effect similar to that derived from the Manufacturers' opioids.

238. Columbus became the center of the black tar heroin drug market east of the

¹⁷³ See Quinones, Sam. *Dreamland: the True Tale of America's Opiate Epidemic*. Dreamland: the True Tale of America's Opiate Epidemic, Bloomsbury Press, 2016, Chapter 12 ("Collision: Ground Zero").

Mississippi River and was transformed into a major black tar heroin trafficking hub for supplying other U.S. geographical regions, including the Northeast, the Great Lakes, the Midwest, and Appalachia.

239. The rise of black tar heroin in Columbus was caused by the oversaturation of prescription opioids in Columbus.

240. The Manufacturers, Distributors and KOLs knew, or should have known, about the sequence of addiction that leads a pain patient to heroin: as a pain patient takes prescription opioids, their body develops a tolerance such that the dosage regularly needs to be increased; as dosages increase, opioids become more expensive; because opioids are often prescribed for daily use, patients taking prescription opioids quickly spend hundreds, and then thousands, of dollars simply managing their pain.¹⁷⁴ Alternatively, patients may no longer be able to obtain prescriptions for the opioids to which they have become addicted. The Manufacturers, Distributors and KOLs knew or should have known that, because heroin offers a pain patient similar effect to that offered by opioids, and heroin costs far less, a high percentage of patients taking prescription opioids were vulnerable to pivoting their opioid addiction into a heroin addiction.

241. One study revealed that 65% of heroin abusers in Ohio between 18 and 30 entered into heroin use from prescription opioids. While a majority of heroin abusers are former opioid abusers, the inverse is not true: according to a national survey, less than 4% of prescription pain medicine abusers had started by using heroin within five years.¹⁷⁵ The NEJM published an

¹⁷⁴ Nicole Makris, Healthline, “Prescription Drugs Are Leading to Heroin Addictions” (Feb. 26, 2016), <https://www.healthline.com/health-news/prescription-drugs-lead-to-addiction#1> (Quoting a family care physician who has observed that “[a] lot of people get addicted to the [opioid] pills and then progress to heroin because they can’t afford the [opioid] pills.”).

¹⁷⁵ National Institute on Drug Abuse, “Heroin” (Revised July 2017), <https://www.drugabuse.gov/publications/drugfacts/heroin#ref>, citing Muhuri PK, Gfroerer JC, Davies MC., *Associations of Nonmedical Pain Reliever Use*

article examining the relationship between opioids and heroin use. The article concluded that “75% of [heroin] users initiated opioid use with prescription opioids.”¹⁷⁶ These studies draw a direct line between the Manufacturers’, Distributors’ and KOLs’ conduct and the heroin epidemic in the United States, including in Columbus.

242. As opioids have become less available, their price has risen; the inverse is true for heroin.¹⁷⁷ And, as deaths related to prescription opioid medications are starting to fall, deaths related to heroin overdoses are rising.¹⁷⁸

243. Consumers also substituted from prescription opioids to synthetic opioids such as fentanyl.¹⁷⁹ Fentanyl is a synthetic opioid that is 50-100 times more potent than morphine, and 25-50 times more potent than heroin.¹⁸⁰ Because of its higher potency, it takes much less fentanyl for a user to experience the opioid effect – making it far more likely that a user will overdose.¹⁸¹ Fentanyl is so dangerous that China recently banned it.¹⁸²

244. The United States government does not track death rates for every drug. The National Center for Health Statistics (“NCHS”) at the CDC does collect information on many of the more commonly used drugs. The information collected shows a 5.9-fold increase in the total number of deaths from heroin and non-methadone synthetics (including illicit synthetic opioids

and Initiation of Heroin Use in the United States. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2013.

¹⁷⁶ Wilson M. Compton, M.D., M.P.E., Christopher M. Jones, Pharm. D., M.P.H., and Grant T. Baldwin, Ph.D., M.P.H., 374 N Engl J Med 154-63 (Jan. 14, 2016), <http://www.nejm.org/doi/full/10.1056/NEJMra1508490#ref41>.

¹⁷⁷ See, e.g., Eugene Richards, *The New Yorkers, The Addicts Next Door* (June 5, 2017), <https://www.newyorker.com/magazine/2017/06/05/the-addicts-next-door> (“In West Virginia, many addicts told me, an oxycodone pill now sells for about eighty dollars; a dose of heroin can be bought for about ten.”).

¹⁷⁸ Josh Katz, The New York Times, *Short Answers to Hard Questions About The Opioid Crisis* (Aug. 10, 2017), <https://www.nytimes.com/interactive/2017/08/03/upshot/opioid-drug-overdose-epidemic.html#question-3>.

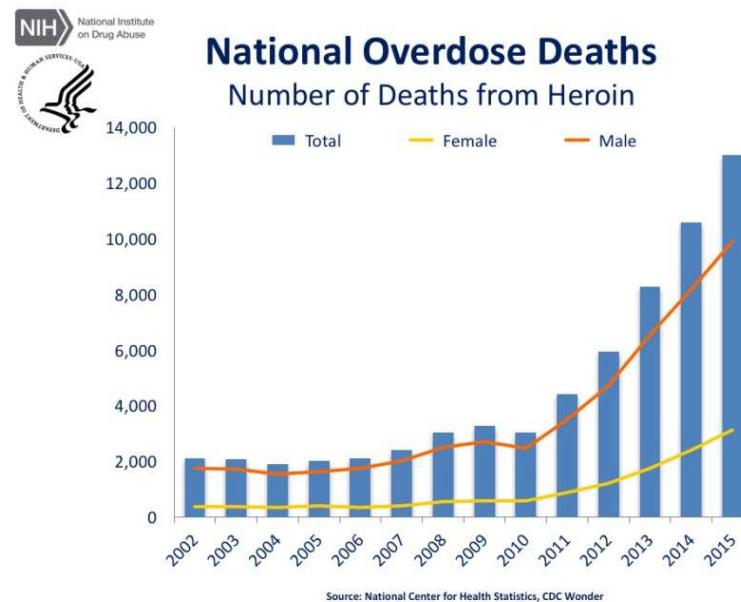
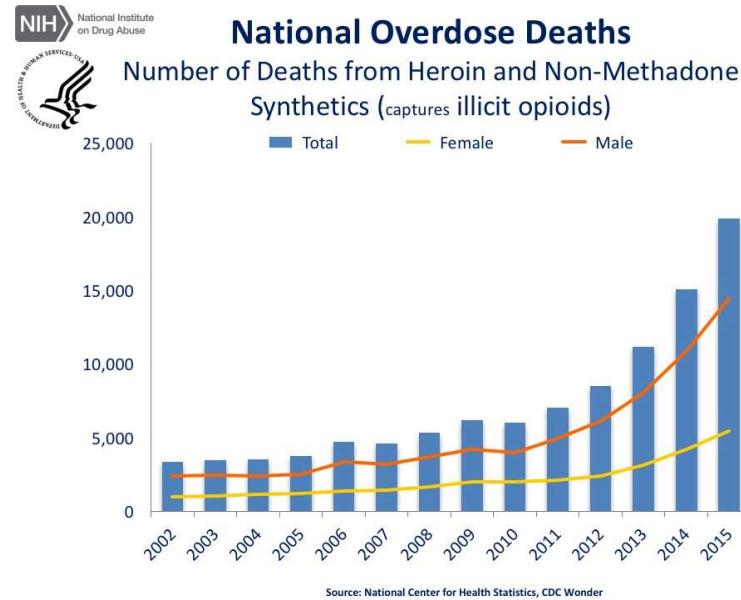
¹⁷⁹ Abby Albert et al., National Board of Economic Research, *Supply-Side Drug Policy in the Presence of Substitutes: Evidence from the Introduction of Abuse-Deterrent Opioids* (January 2017), <http://www.nber.org/papers/w23031>.

¹⁸⁰ Alice G. Walton, Forbes, *Why Fentanyl Is So Much More Deadly Than Heroin* (April 9, 2016), <https://www.forbes.com/sites/alicegwalton/2016/04/09/why-fentanyl-is-so-much-more-deadly-than-heroin/#670fcc3a7f6a>.

¹⁸¹ *Id.*

¹⁸² Sara Ganim, CNN, *China’s fentanyl ban a ‘game-changer’ for opioid epidemic, DEA officials say* (Feb. 16, 2017), <http://www.cnn.com/2017/02/16/health/fentanyl-china-ban-opioids/index.html>.

such as fentanyl) from 2002 to 2015, as well as a 6.2-fold increase in the total number of deaths from heroin since 2002 to 2015.¹⁸³



245. The dramatic rise of this epidemic is illustrated by the fact that between 2005 and 2009, Mexican heroin production increased by more than 600%. And between 2010 and 2014,

¹⁸³ National Institute on Drug Abuse, “Overdose Death Rates,” Revised September 2017, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>.

the amount of heroin seized at the U.S.-Mexico border more than doubled. Overall, global poppy cultivation has hit its highest level since the 1930s.¹⁸⁴

246. The average life span of someone addicted to heroin is approximately fifteen (15) years less than the average person.¹⁸⁵

VI. COLUMBUS HAS BEEN, AND WILL CONTINUE TO BE, HARMED AND DAMAGED BY THE OPIOID EPIDEMIC CREATED BY DEFENDANTS.

247. As a result of the Manufacturers', Distributors' and KOLs' actions, Columbus has suffered significant and ongoing harm and damages.

A. While The Opioid Epidemic Is A National Issue, The Statistics Are Particularly Tragic In Columbus.

248. While the opioid epidemic is affecting communities throughout the country, Columbus has felt its impact, and will continue to feel its impact, more than others.

249. Columbus is the fourteenth largest city in the United States.

250. The State of Ohio leads the nation in deaths related to heroin and synthetic opioids, despite being only the seventh most populous state. Approximately one in nine heroin deaths across the U.S. happened in Ohio (1,208 out of 10,574), and approximately one in fourteen synthetic opioid deaths happened in Ohio (590 deaths out of 5,544).¹⁸⁶

251. In Franklin County, Columbus' home county, there has been a 396% increase in residents who have died from unintentional drug overdoses from 2003 to 2016.¹⁸⁷ Over 300 residents of Franklin County died from unintentional drug overdoses in 2016 alone, surpassing

¹⁸⁴ New York Times, "The Numbers Behind America's Heroin Epidemic" (Oct. 30, 2015), <https://www.nytimes.com/interactive/2015/10/30/us/31heroin-deaths.html?mcubz=0>.

¹⁸⁵ Breda Smith, et al., Journal of Addictive Diseases, *Life Expectancy and Productivity Loss Among Narcotics Addicts Thirty-Three Years After Index Treatment*, 2006, https://aran.library.nuigalway.ie/bitstream/handle/10379/2342/2006_ja_smyth_narcotics_j_of_addictive_diseases.pdf?sequence=1&isAllowed=y.

¹⁸⁶ Catherine Candisky and Alan Johnson, *Ohio Leads Nation In Overdose Deaths*, Columbus Dispatch (Nov. 29, 2016), <http://www.dispatch.com/news/20161129/ohio-leads-nation-in-overdose-deaths/1>.

¹⁸⁷ Columbus Department of Public Health, "Opiate Crisis Quarterly Report, April-June 2017" (Oct. 2017), available at <https://www.columbus.gov/publichealth/programs/Office-of-Epidemiology/Harm-Reduction/>.

the number of deaths in 2015.¹⁸⁸

252. For every opioid-related death, 10 people are admitted for treatment, 32 people visited the emergency room, 130 people are classified as abusers or drug-dependent, and 825 people use opioids for non-medical purposes.¹⁸⁹

253. A study by the Ohio Department of Health revealed a 97.9% correlation between the number of opioids prescribed in Ohio and the number of accidental drug overdoses (including from prescription opioids and heroin).¹⁹⁰ From this information, statisticians approximate that for every two months' worth of opioids that Defendants marketed and distributed into Columbus, someone died.¹⁹¹

254. The opioid addiction epidemic is directly devastating the children of Columbus. It is estimated that more than 5,000 children in Franklin County between the ages of 12 and 17 have used prescription medication such as opioids for non-medical use.¹⁹² Further, from July 2016 to June 2017, 268 babies were treated in Franklin County for neonatal abstinence syndrome, a syndrome associated with opioid withdrawal.¹⁹³

255. Related to the devastation to families is the devastation to neighborhoods. Neighborhoods have been devastated by the crisis and need to be revitalized through various methods, including the creation of Community Centers.

256. Treatment is complex and needs to be customized to meet individuals needs,

¹⁸⁸ *Id.*

¹⁸⁹ City of Columbus and Franklin County, "Franklin County Opiate Action Plan" (2017), https://www.myfcph.org/pdfs/OpiateReports/Opiate%20Action%20Plan_0617.pdf.

¹⁹⁰ Emma Ockerman, The Post, *Ohio In Crisis*, <http://projects.thepostathens.com/SpecialProjects/opioid-epidemic-ohio-in-crisis/index.html>.

¹⁹¹ Quinones, Sam. *Dreamland: the True Tale of America's Opiate Epidemic*. Dreamland: the True Tale of America's Opiate Epidemic, Bloomsbury Press, 2016, p. 252.

¹⁹² City of Columbus and Franklin County, "Franklin County Opiate Action Plan" (2017), https://www.myfcph.org/pdfs/OpiateReports/Opiate%20Action%20Plan_0617.pdf, citing Journal of Addictive Diseases, *Nonmedical Use of Prescription Opioids Among Adolescents: Subtypes Based on Motivation for Use* (2012).

¹⁹³ Columbus Department of Public Health, "Opiate Crisis Quarterly Report, April-June 2017" (Oct. 2017), available at <https://www.columbus.gov/publichealth/programs/Office-of-Epidemiology/Harm-Reduction/>.

including, but not limited to, housing, employment, education, care for affected family members, physical and mental health issues, support groups such as Narcotics Anonymous and faith based support.

257. Columbus also needs to be able to treat the persons addicted and affected by opioids, including, but not limited to, through the funding, implementation and/or construction of treatment centers and facilities, medication assisted treatment, recovery support, community based support and through funding, equipping and educating existing health care facilities.

B. The Manufacturers', Distributors' And KOL's Conduct Has Increased Columbus' Health Care Costs.

258. The Manufacturers', Distributors' and KOL's misrepresentations regarding the purported safety and efficacy of opioids, and their failure to properly limit shipments, have increased Columbus's health care costs. Columbus provides health insurance to its employees and their beneficiaries, and has administrative services-only agreements with two different insurers. This means that when anyone covered by Columbus's health insurance program visits a doctor, fills a prescription or otherwise incurs covered health-related costs, Columbus pays a portion of those costs directly.

259. Columbus provides health insurance to more than 8,200 people.¹⁹⁴ From 2010 to 2016, Columbus health insurance costs increased from \$107 million to \$177.2 million, a 65.6 percent increase.¹⁹⁵ In 2016, Columbus's prescription drug coverage made up \$40.4 million of the total insurance cost.¹⁹⁶

260. Columbus incurs increased costs for its employees' prescriptions for opioids that would have not been prescribed but for the misrepresentations made by the Manufacturers and

¹⁹⁴ Lucas Sullivan, The Columbus Dispatch, *Health costs jump 11.5% to cover Columbus city employees* (Jan. 13, 2016), available at: <http://www.dispatch.com/content/stories/local/2016/01/13/11-5-jump-in-health-costs-okd.html>.

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

KOLs to doctors in Columbus. The direct costs of filling employees' opioid prescriptions is a part of the total cost to Columbus for prescriptions of opioids, which includes, but is not limited to, costs for doctors' visits and lab work. Had Defendants told the truth about the risks and benefits of opioids, and/or properly reported suspicious orders, Columbus would not have had to pay for these drugs or the costs related to their prescription.

C. The Opioid Crisis Caused By The Manufacturers, The Distributors And The KOLs Has Caused Columbus To Incur Damages Providing Human Services In An Effort To Abate The Opioid Epidemic.

261. The effects of the opioid epidemic reach across Columbus, imposing additional human and financial costs at all levels. For example, Columbus has spent, and will continue to spend, significant resources helping its homeless population by directly providing key services or funding programs run by charitable organizations. Such human services include housing, shelters, and mental health counseling, among others.

262. Over the past decade, the homeless population in Columbus has grown. From 2010 to 2014, for example, overall family homelessness fell 15 percent nationwide – but rose 7.6 percent in Columbus.¹⁹⁷

263. The increase in Columbus has been caused, at least in part, by the opioid epidemic, as people addicted to opioids often find it difficult to hold down jobs, which ultimately pushes them on to the street and places a huge burden onto the City. Providing the homeless population in Columbus with shelter, treatment, and other services is an expensive undertaking, made dramatically more so now that the homeless population has grown and is comprised of a large number of addicts.

264. For many persons, a valid prescription for opioids was the first step to addiction

¹⁹⁷ Rick Rouan, The Columbus Dispatch, *Number of homeless families rising in Franklin County, report says* (Sept. 22, 2015), http://www.dispatch.com/content/stories/local/2015/09/22/Report_shows_more_homeless_families.html.

and drug abuse, which ultimately led to the loss of their homes. Some young people living on the streets of Columbus today ran away from homes that had fallen apart because a parent had become addicted to opioids. According to the Public Children Services Association of Ohio, 70% of children under the age of one who are in custody of Children Services have opioid-involved parents.¹⁹⁸

265. The oversaturation of prescription opioids has not only helped to fuel the homeless crisis, but it has made it immeasurably more difficult for Columbus to address. Mental health services, for example, are critical for many in the homeless population. Unfortunately, opioid use and addiction can make it more difficult to provide effective mental health treatment. Those who need help most often turn to opioids to self-medicate, and avoid getting treatment and care that might lead to long-term success. As a result, Columbus needs to provide additional mental health facilities and treatment options.

266. Because opioid addition is highly prevalent in Columbus, the City has had to invest significant resources in addiction programs and other human services, which are widely used by all residents of Columbus, whether homeless or not.

267. Columbus also is investing heavily in prevention work, running programs at local schools and sponsoring events aimed at teaching people how to avoid becoming addicted to opioids and how to help friends and family do the same.

268. For example, the Columbus Department of Public Health works with City Schools and community centers in regard to prevention.

¹⁹⁸ City of Columbus and Franklin County, “Franklin County Opiate Action Plan: Building the Bridge to Tomorrow,” https://www.myfcph.org/pdfs/OpiateReports/Opiate%20Action%20Plan_0617.pdf, citing Public Children Services Association of Ohio, *The Opioid Epidemic’s Impact on Children Services in Ohio 2017*.

D. Columbus Already Has Incurred Significant Damages Relating To Police And Fire Responses To The Opioid Issues, And Will Continue To Do So, In An Effort to Abate The Epidemic.

269. The Columbus Department of Public Safety acts as a response unit to specific issues caused by the opioid epidemic. It includes both the Columbus Division of Fire and the Columbus Division of Police.

1. The Columbus Division of Fire has incurred significant damages responding to opioid issues due to the actions of the Manufacturers, the Distributors and the KOLs.

270. The Columbus Division of Fire provides emergency medical services in the City of Columbus. The Division of Fire responds to emergency calls, dispatching emergency medical service personnel, including emergency medical technicians, or EMTs, in ambulances or fire trucks.

271. Although providing emergency medical services is expensive, it is one of the most critical services the City provides its citizens. The Division of Fire is the front-line responder for a wide range of medical emergencies, from heart attacks and strokes to mental health emergencies and drug overdoses.

272. Over the past decade, the number of opioid-related emergency calls to which the Fire Department has responded has risen sharply. For example, in 2016, the Division of Fire administered over 3,800 doses (over ten doses per day) of naloxone, a powerful medicine given to counteract an opioid-related overdose.¹⁹⁹ This rate, over ten doses per day, has increased

¹⁹⁹ Columbus Department of Public Health, “Opiate Crisis Quarterly Report, Jan.-March 2016” (August 2016), http://www.myfcph.org/pdfs/OpiateReports/DrugOD_Q1_01-03_16.pdf; Columbus Department of Public Health, “Opiate Crisis Quarterly Report, April-June 2016” (September 2016), http://www.myfcph.org/pdfs/OpiateReports/DrugOD_Q2_04-06_16.pdf; Columbus Department of Public Health, “Opiate Crisis Quarterly Report, July-Sept. 2016” (December 2016), http://www.myfcph.org/pdfs/OpiateReports/DrugOD_Q3_12_21_16.pdf; Columbus Department of Public Health, “Opiate Crisis Quarterly Report, Oct.-Dec. 2016” (March 2017), http://www.myfcph.org/pdfs/OpiateReports/OpiateQuarterly_Q4_3_27_17.pdf.

dramatically since 2011, when the average number of doses administered per day was 6.55.²⁰⁰

273. From July 2016 through June 2017, the Division of Fire reported 3,115 patients with drug overdoses who were treated by EMS with at least one dose of naloxone.²⁰¹

274. In the last four years, the number of times the Division of Fire was dispatched for an emergency drug overdose increased by more than 20 percent.²⁰² The Division of Fire also established the Rapid Response Emergency Addiction and Crisis Team (RREACT) to assist overdose patients with accessing treatment and other social services.

275. Responding to opioid overdoses is expensive; it involves sending ambulances, engines, and specially-trained staff to the emergency. People who have overdosed on opioids typically require at least one, if not several, doses of naloxone, each of which carries a significant price tag. Then the patient must be transported to the emergency room where City employees typically must wait while the patient is treated. The costs of materials, maintenance, medication, and time are significant. Additional resources are needed to pay for the emergency services costs caused by the opioid epidemic.

276. In 2016, the Division of Fire administered naloxone over 3,800 times.²⁰³ That means that nearly every two hours, Columbus EMTs saved the life of someone who had overdosed on opioids. And the overall increase in the volume of calls means each first responder is responding to ever-increasing numbers of emergency incidents. This dramatic rise in the number and intensity of emergency incidents has significant effects on the emergency responders.

²⁰⁰ City of Columbus and Franklin County, “Franklin County Opiate Action Plan” at 8, <https://octf.franklincountyohio.gov/CRNR-OCTF-website/media/Documents/2017%20Opiate%20Action%20Plan/2017-Opiate-Action-Plan-Web.pdf>

²⁰¹ Columbus Department of Public Health, “Opiate Crisis Quarterly Report, April-June 2017” (Oct. 2017), available at <https://www.columbus.gov/publichealth/programs/Office-of-Epidemiology/Harm-Reduction/>.

²⁰² Columbus Department of Public Health, “Opiate Crisis Quarterly Report, Jan.-March 2017” (June 2017), citing Columbus Division of Fire statistics.

²⁰³ See *supra* note 205.

2. The Columbus Division of Police has incurred significant damages responding to opioid issues due to the actions of the Manufacturers, the Distributors and the KOLs.

277. Because not all addicts receive the help they need, opioid addiction is killing Columbus' citizens at an alarming rate. For example, fentanyl kills at least one person every day in Franklin County.²⁰⁴

278. Fentanyl's deadly presence is caused by those who are addicted seeking alternatives to prescription opioids once they no longer can obtain them. From 2013 to 2015, the number of law enforcement drug seizures of fentanyl increased more than thirty-five fold, from 110 in 2013 to 3,882 in 2015.²⁰⁵

279. The opioid epidemic has forced the Columbus Division of Police to expend significant resources fighting drug trafficking in Columbus. In the 2000s, as prescription opioids and heroin became the kings of the drug trade, illegal drug trafficking in Columbus rose significantly. Combating this rise in drug trafficking has forced the City to put more officers on the street and assign more detectives to work these drug cases in an effort to abate the epidemic.

280. Columbus is just beginning to experience the full impact of Defendants' actions, as addicted persons inevitably turn to heroin and fentanyl. Columbus' injury is ongoing, and promises to continue for many years before it is abated.

281. Increased illegal drug trafficking also has caused a rise in other criminal activities in Columbus. The price of prescription opioids on the black market is significant, forcing many addicts to turn to burglary or other property crimes in order to pay for their addiction.

282. Not only does the opioid epidemic impair the quality of life for everyone in

²⁰⁴ Alan Johnson and Catherine Candisky, The Columbus Dispatch, *Fentanyl, a ruthless, indiscriminate killer, taking a big toll in Ohio* (April 23, 2017), <http://www.dispatch.com/news/20170423/fentanyl-ruthless-indiscriminate-killer-taking-big-toll-in-ohio>.

²⁰⁵ City of Columbus and Franklin County, "Franklin County Opiate Action Plan" at 8, <https://octf.franklincountyohio.gov/CRNR-OCTF-website/media/Documents/2017%20Opiate%20Action%20Plan/2017-Opiate-Action-Plan-Web.pdf>.

Columbus, the City is forced to address these crimes, expending police, surveillance, field testing, lab and investigatory resources and additional manpower, all of which have direct costs to the City. For example, from 2009 through 2015, both property crimes and retail theft increased. In 2015, central Ohio shoplifters stole a record amount of merchandise from retailers.²⁰⁶ In 2009, 58 percent of theft charges involved repeat offenders; by 2015, that number had risen to 81 percent.²⁰⁷ The increase in property crime has been attributed to the heroin and opioid addiction epidemic.²⁰⁸

283. As Columbus expends significant resources to address increased drug trafficking and property crimes, it has had to divert resources from other public safety issues.

284. The opioid epidemic also has increased public safety costs and needs in other aspects. For example, Columbus bears significant costs related to an increased number of arrests for opioid-related crimes. This alone has placed a serious strain on Columbus' police resources, and individuals who are addicted to opioids present special challenges to law enforcement.

285. Often, individuals in active use of opioids may need medical care, including, but limited to, transportation to a medical center. This requires removing an officer from her or his beat to take the individual to the hospital and wait there during a recovery period, thus effectively removing that officer from the remainder of her or his shift.

286. Additional harm has been caused to Columbus in the form of additional costs to, and needs of, the City's Justice system. Many more opioid related or caused cases now fill the court's dockets. Diversion programs are needed to assist with the excess. Additionally, due to the damage done to families, domestic issues have increased. The creation of Community

²⁰⁶ Tim Feran, The Columbus Dispatch, *Shoplifting a plague on central Ohio in 2015* (Jan. 15, 2016), <http://www.dispatch.com/content/stories/business/2016/01/15/shoplifting-a-plague-on-central-ohio-in-15.html>.

²⁰⁷ *Id.*

²⁰⁸ *Id.*

Liaison Officers and partnerships with local domestic courts and Family Services agencies are needed to address the problems created by the opioid epidemic.

287. The opioid epidemic created by the Defendants has caused Columbus serious and ongoing harm. The City's costs for public safety, human and public services, and law enforcement have all risen dramatically, and the City as a community has suffered serious and tragic consequences as a result.

288. The opioid epidemic also will cause Columbus to incur significant damages going forward in an effort to end, alleviate and abate the issues caused by the epidemic.

VII. THE MANUFACTURERS, DISTRIBUTORS AND KOLS HAVE REAPED, AND WILL CONTINUE TO REAP, ENORMOUS PROFITS WHILE THE NATION, AND COLUMBUS, ARE FORCED TO REMEDY AND ABATE THE OPIOID EPIDEMIC.

289. The Manufacturers, Distributors and KOLs have reaped enormous profits from the addiction epidemic they spawned.

290. The Distributors generate substantial revenue from the distribution of opioids. In 2015, for example, U.S. revenues from the Distributors' respective drug distribution divisions totaled \$378.4 billion, a 14.8% increase from 2014.²⁰⁹ The Distributors' collective drug distribution revenues totaled approximately \$406.5 billion in 2016, and are expected to reach \$424.9 billion in 2017.²¹⁰ Broken down for 2016, McKesson's revenues in 2016 totaled \$153.8 billion; AmerisourceBergen's revenues in 2016 totaled \$142.1 billion; and Cardinal Health's revenues totaled \$110.5 billion.²¹¹ The Distributors account for roughly 90% of all revenues from drug distributions in the United States.²¹²

²⁰⁹ Brian McCullough, Daily Local News, *AmerisourceBergen draws heat for opioid distributions* (March 6, 2017), <http://www.dailylocal.com/article/DL/20170306/BUSINESS/170309882>.

²¹⁰ Adam J. Fein, Ph.D., MDM, "MDM Market Leaders | Top Pharmaceutical Distributors," <https://www.mdm.com/2017-top-pharmaceuticals-distributors>.

²¹¹ *Id.*

²¹² *Id.*

291. The Manufacturers also are reaping billions of dollars from opioids. In 2014 alone, the American opioid market generated \$11 billion in revenue for individuals and companies like Manufacturers – a number expected to rise to \$17.7 billion by 2021.²¹³

292. In fact, Purdue has generated estimated sales of more than \$35 billion from opioids since 1996, while making profits of more than \$3 billion in 2015 alone.

293. Purdue's annual opioid sales of \$3 billion in 2015 represent a four-fold increase from its 2006 sales of \$800 million.

294. Endo has also profited massively from the sale of opioids. Opioids accounted for more than \$400 million in 2012, and Opana ER alone generated more than \$1 billion in revenue for Endo from 2010 to 2013.

295. Janssen also generates substantial sales from its opioids. For example, Duragesic accounted for more than \$1 billion in sales in 2009, and Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

296. The Manufacturers, the Distributors and the KOLs will continue to reap enormous profits.

VIII. FRAUDULENT CONCEALMENT.

297. At all times relevant to this Complaint, the Manufacturers, Distributors and KOLs took steps to avoid detection of, and fraudulently conceal, their conduct.

298. The Manufacturers and KOLs disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through the Front Groups. The Manufacturers and KOLs purposefully hid behind these organizations to avoid regulatory scrutiny and to prevent doctors and the public from discounting their messages.

²¹³ Alyangka Francheska Manalo, GuruFocus, *Companies Aiming for the Billion-Dollar Opioid Addiction Market* (March 18, 2017), <https://www.gurufocus.com/news/493086/companies-aiming-for-the-billion-dollar-opioid-addiction-market>.

299. While the Manufacturers and KOLs were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and exerting final approval over their content. The Manufacturers and KOLs exerted their considerable influence on these promotional and “educational” materials.

300. In addition to hiding their own role in generating the deceptive content, the Manufacturers and KOLs manipulated their promotional materials and the scientific literature to make it appear as if they were accurate, truthful, and supported by substantial scientific evidence. The Manufacturers and KOLs distorted the meaning or import of studies they cited and offered them as evidence for propositions they did not actually support. The true lack of support for Manufacturers’ and KOLs’ deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions, nor could they have been detected by Columbus.

301. The Manufacturers and KOLs, in furtherance of their respective marketing strategies, intentionally concealed their own role in causing the opioid epidemic. The Manufacturers and KOLs successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the existence of claims that Columbus now asserts. Columbus was not alerted to the existence and scope of the Manufacturers’ and KOLs’ industry-wide misrepresentations and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

302. The Distributors also concealed their role in the epidemic. Initially, they represented that they were complying with all applicable laws. In regard to the various settlements and consent orders discussed above, the Distributors nowhere admitted liability or wrongdoing. In fact, to this day, the Distributors claim they currently, and always have,

followed the law. It is only recently that their liability and wrongdoing have come to light.

303. The Distributors knew, or should have known, their conduct was not in compliance with the law.

304. Columbus has acted diligently at all times in investigating and bringing this suit.

305. Through their public statements, marketing, and advertising, and concealment of their wrongdoing, the Manufacturers', Distributors', and KOLs' deceptions deprived Columbus of actual or presumptive knowledge of facts sufficient to put them on notice of potential claims.

COUNT ONE: PUBLIC NUISANCE (COMMON LAW)
(AGAINST ALL DEFENDANTS)

306. Columbus incorporates by reference paragraphs 1 through 305 of this Complaint as if fully set forth herein, and further alleges as follows.

307. Columbus brings this claim under Ohio common law for recovery related to the abatement of the continuing public nuisance created by the Defendants. As a direct result of the Defendants' conduct, Columbus has suffered actual injury and damages related to abating the nuisance caused by the Defendants. Columbus seeks recovery for its own harm. Columbus does not seek damages in this Count for death, physical injury to person, emotional distress and/or physical damages to property.

308. The Defendants individually, and in conjunction with each other, have caused a significant and unreasonable interference with the public health, safety, welfare, peace, comfort and convenience, as well as the ability for Columbus residents to be free from disturbance and reasonable apprehension of danger to person or property.

309. The Defendants intentionally, unlawfully, and recklessly manufactured, distributed, marketed, and sold prescription opioids, and continue to do so, in a manner and in quantities that the Defendants knew, or reasonably should have known, would result in the

oversaturation of opioids throughout the Columbus, addiction, drug abuse, an elevated level of crime, death and injuries to Columbus residents, a higher level of fear, discomfort and inconvenience to the residents of Columbus, and direct costs to the City itself.

310. The nuisance and harm caused to Columbus as a direct result of the Defendants' conduct described above, includes, but is not limited to:

- a. It is estimated that in calendar year 2016 alone, health care providers wrote more than 289 million prescriptions for opioid pain medication, *i.e., enough for every adult in the United States to have more than one bottle of pills*. This has in turn caused an epidemic of addiction, as well as crime, broken families and devastation to communities, including Columbus.
- b. 300 residents of Franklin County died from unintentional drug overdoses in 2016 alone.²¹⁴ Related to this, generally, for every opioid-related death, 10 people are admitted for treatment, 32 people visit the emergency room, 130 people are classified as abusers or drug-dependent, and 825 people use opioids for non-medical purposes.²¹⁵
- c. It is estimated that more than 5,000 children in Franklin County between the ages of 12 and 17 have used prescription medication such as opioids for non-medical use. On information and belief, the majority of these children are from Columbus.²¹⁶
- d. According to the Public Children Services Association of Ohio, 70% of children under the age of one who are in custody of Children Services have opioid-involved parents.²¹⁷
- e. From July 2016 to June 2017, 268 babies were treated in Franklin County for neonatal abstinence syndrome, a condition associated with opioid withdrawal. On information and belief, the majority of these children were from the Columbus.²¹⁸

²¹⁴ Columbus Department of Public Health, "Opiate Crisis Quarterly Report, Jan-March 2017" (June 2017), http://www.myfcph.org/pdfs/OpiateReports/OpiateQuarterly_2017Q1.PDF.

²¹⁵ City of Columbus and Franklin County, "Franklin County Opiate Action Plan" (2017), https://www.myfcph.org/pdfs/OpiateReports/Opiate%20Action%20Plan_0617.pdf.

²¹⁶ *Id.*, citing Journal of Addictive Diseases, *Nonmedical Use of Prescription Opioids Among Adolescents: Subtypes Based on Motivation for Use*, 2012)

²¹⁷ City of Columbus and Franklin County, "Franklin County Opiate Action Plan: Building the Bridge to Tomorrow," https://www.myfcph.org/pdfs/OpiateReports/Opiate%20Action%20Plan_0617.pdf, citing Public Children Services Association of Ohio, *The Opioid Epidemic's Impact on Children Services in Ohio 2017*.

²¹⁸ Columbus Department of Public Health, "Opiate Crisis Quarterly Report, Jan.-March 2017" (June 2017).

- f. Neighborhoods have been devastated.
- g. Persons in Columbus and surrounding communities are addicted to, and affected by, opioids.
- i. Columbus has lost employee and resident productivity.
- j. The homeless population has increased, as has the resulting necessity to provide housing, shelters, treatment and mental health counseling. From 2010 to 2014, for example, overall family homelessness fell 15 percent nationwide – but rose 7.6 percent in Columbus.²¹⁹
- k. Individuals who have become addicted to prescription opioids, but cannot afford their increased costs or are unable to secure a prescription, have turned to cheaper, more potent, and more dangerous alternatives, including heroin and fentanyl. While a majority of heroin abusers are former opioid abusers, the inverse is not true: according to a national survey, less than 4% of prescription pain medicine abusers had started by using heroin.²²⁰
- l. A mental health crisis has been created.
- m. Increased demands have been created on the Columbus Division of Fire. In 2016 alone, the Division of Fire administered over 3,800 doses (over ten doses per day) of naloxone, a powerful medicine given to counteract an opioid-related overdose.²²¹ From July 2016 through June 2017, the Division of Fire reported 3,115 patients with drug overdoses who were treated by EMS with at least one dose of naloxone.²²²

²¹⁹ Rick Rouan, The Columbus Dispatch, *Number of homeless families rising in Franklin County, report says* (Sept. 22, 2015), http://www.dispatch.com/content/stories/local/2015/09/22/Report_shows_more_homeless_families.html.

²²⁰ National Institute on Drug Abuse, “Heroin” (Revised July 2017), <https://www.drugabuse.gov/publications/drugfacts/heroin#ref>, citing Muhuri PK, Gfroerer JC, Davies MC., *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2013.

²²¹ Columbus Department of Public Health, “Opiate Crisis Quarterly Report, Jan.-March 2016” (August 2016), http://www.myfcph.org/pdfs/OpiateReports/DrugOD_Q1_01-03_16.pdf; Columbus Department of Public Health, “Opiate Crisis Quarterly Report, April-June 2016” (September 2016), http://www.myfcph.org/pdfs/OpiateReports/DrugOD_Q2_04-06_16.pdf; Columbus Department of Public Health, “Opiate Crisis Quarterly Report, July-Sept. 2016” (December 2016), http://www.myfcph.org/pdfs/OpiateReports/DrugOD_Q3_12_21_16.pdf; Columbus Department of Public Health, “Opiate Crisis Quarterly Report, Oct.-Dec. 2016” (March 2017), http://www.myfcph.org/pdfs/OpiateReports/OpiateQuarterly_Q4_3_27_17.pdf.

²²² Columbus Department of Public Health, “Opiate Crisis Quarterly Report, April-June 2017” (Oct. 2017), available at <https://www.columbus.gov/publichealth/programs/Office-of-Epidemiology/Harm-Reduction/>

n. Increased demands have been created on the Columbus Division of Police. As opioid-addicted persons turn to heroin and fentanyl to fuel their needs, the harm to Columbus is ongoing and promises to continue for many years. Increased illegal drug trafficking has caused a rise in other criminal activities in Columbus. Not only does this impair the quality of life for everyone in Columbus, Columbus is forced to address these crimes through police work, surveillance, field testing, lab and investigatory resources, prosecution, diversion programs, and additional manpower.

311. The Defendants' ongoing conduct produces a continuing nuisance, leading to abuse, misuse, addiction, crime, and public health issues which must be abated to prevent injury and annoyance. The Defendants' conduct directly impacted, and continues to impact, persons in Columbus, and is likely to cause significant harm in the future.

312. The Defendants knew, or reasonably should have known, that their conduct described in this Complaint would cause addiction, and otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance. But for the Defendants' individual and/or combined conduct, these harms would not have occurred.

313. The Defendants knew, or reasonably should have known, that persons would rely to their detriment on the Defendants' misrepresentations, omissions and other statements described in this Complaint.

314. It is, or should be, reasonably foreseeable to the Defendants that their conduct will continue to cause harm to Columbus in the future, and, unless abated, will otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance.

315. The Defendants acted with actual malice because the Defendants acted intentionally and/or with a conscious disregard for the rights and safety of other persons, and said

actions have a great probability of causing substantial harm and have created an absolute nuisance.

316. The damages available to Columbus include, *inter alia*, recoupment of damages flowing from an ongoing and persistent public nuisance that the government seeks to abate. The Defendants' conduct is ongoing and persistent, and Columbus seeks all damages flowing from the Defendants' conduct. Columbus further seeks to abate the continuing nuisance and harm created by the Defendants' conduct into the future.

317. Columbus seeks all legal and equitable relief as allowed by law, including *inter alia*, abatement, abatement costs, available compensatory damages, and available punitive damages related to the absolute and continuing public nuisance the Defendants created, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT TWO: PUBLIC NUISANCE (O.R.C. § 715.44)
(AGAINST ALL DEFENDANTS)

318. Columbus incorporates by reference paragraphs 1 through 317 of this Complaint as if fully set forth herein, and further alleges as follows.

319. Columbus brings this claim pursuant to O.R.C. § 715.44 for recovery related to the abatement of the continuing public nuisance created by the Defendants. As a direct result of the Defendants' conduct, Columbus has suffered actual injury and damages related to abating the nuisance caused by the Defendants. Columbus seeks recovery for its own harm. Columbus does not seek damages in this Count for death, physical injury to person, emotional distress and/or physical damage to property.

320. The Defendants individually, and in conjunction with each other, have caused a significant and unreasonable interference with public health, safety, welfare, peace, comfort and convenience, as well as the ability for Columbus residents to be free from disturbance and

reasonable apprehension of danger to person or property.

321. The Defendants intentionally, unlawfully, and recklessly manufactured, distributed, marketed, and sold prescription opioids, and continue to do so, in a manner and in quantities that the Defendants knew, or reasonably should have known, would result in the oversaturation of opioids throughout the Columbus, addiction, drug abuse, an elevated level of crime, death and injuries to Columbus residents, a higher level of fear, discomfort and inconvenience to the residents of Columbus, and direct costs to the City itself.

322. The nuisance and harm caused to Columbus as a direct result of the Defendants' conduct described above, includes, but is not limited to:

- a. It is estimated that in calendar year 2016 alone, health care providers wrote more than 289 million prescriptions for opioid pain medication, *i.e., enough for every adult in the United States to have more than one bottle of pills*. This has in turn caused an epidemic of addiction, as well as crime, broken families and devastation to communities, including Columbus.
- b. 300 residents of Franklin County died from unintentional drug overdoses in 2016 alone.²²³ Related to this, generally, for every opioid-related death, 10 people are admitted for treatment, 32 people visit the emergency room, 130 people are classified as abusers or drug-dependent, and 825 people use opioids for non-medical purposes.²²⁴
- c. It is estimated that more than 5,000 children in Franklin County between the ages of 12 and 17 have used prescription medication such as opioids for non-medical use. On information and belief, the majority of these children are from Columbus.²²⁵
- d. According to the Public Children Services Association of Ohio, 70% of children under the age of one who are in custody of

²²³ Columbus Department of Public Health, "Opiate Crisis Quarterly Report, Jan-March 2017" (June 2017), http://www.myfcph.org/pdfs/OpiateReports/OpiateQuarterly_2017Q1.PDF.

²²⁴ City of Columbus and Franklin County, "Franklin County Opiate Action Plan" (2017), https://www.myfcph.org/pdfs/OpiateReports/Opiate%20Action%20Plan_0617.pdf.

²²⁵ *Id.*, citing Journal of Addictive Diseases, *Nonmedical Use of Prescription Opioids Among Adolescents: Subtypes Based on Motivation for Use*, 2012.

Children Services have opioid-involved parents.²²⁶

- e. From July 2016 to June 2017, 268 babies were treated in Franklin County for neonatal abstinence syndrome, a condition associated with opioid withdrawal. On information and belief, the majority of these children were from the Columbus.²²⁷
- f. Neighborhoods have been devastated.
- g. Persons in Columbus and surrounding communities are addicted to, and affected by, opioids.
- ii. Columbus has lost employee and resident productivity.
- j. The homeless population has increased, as has the resulting necessity to provide housing, shelters, treatment and mental health counseling. From 2010 to 2014, for example, overall family homelessness fell 15 percent nationwide – but rose 7.6 percent in Columbus.²²⁸
- k. Individuals who have become addicted to prescription opioids, but cannot afford their increased costs or are unable to secure a prescription, have turned to cheaper, more potent, and more dangerous alternatives, including heroin and fentanyl. While a majority of heroin abusers are former opioid abusers, the inverse is not true: according to a national survey, less than 4% of prescription pain medicine abusers had started by using heroin.²²⁹
- l. A mental health crisis has been created.
- m. Increased demands have been created on the Columbus Division of Fire. In 2016 alone, the Division of Fire administered over 3,800 doses (over ten doses per day) of naloxone, a powerful medicine given to counteract an opioid-related overdose.²³⁰ From July 2016

²²⁶ City of Columbus and Franklin County, “Franklin County Opiate Action Plan: Building the Bridge to Tomorrow,” https://www.myfcph.org/pdfs/OpiateReports/Opiate%20Action%20Plan_0617.pdf, citing Public Children Services Association of Ohio, *The Opioid Epidemic’s Impact on Children Services in Ohio 2017*.

²²⁷ Columbus Department of Public Health, “Opiate Crisis Quarterly Report, Jan.-March 2017” (June 2017).

²²⁸ Rick Rouan, The Columbus Dispatch, *Number of homeless families rising in Franklin County, report says* (Sept. 22, 2015), http://www.dispatch.com/content/stories/local/2015/09/22/Report_shows_more_homeless_families.html.

²²⁹ National Institute on Drug Abuse, “Heroin” (Revised July 2017), <https://www.drugabuse.gov/publications/drugfacts/heroin#ref>, citing Muhuri PK, Gfroerer JC, Davies MC., *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2013.

²³⁰ Columbus Department of Public Health, “Opiate Crisis Quarterly Report, Jan.-March 2016” (August 2016), [http://www.myfcph.org/pdfs/OpiateReports/DrugOD_Q1_01-03_16.pdf](https://www.myfcph.org/pdfs/OpiateReports/DrugOD_Q1_01-03_16.pdf); Columbus Department of Public Health, “Opiate Crisis Quarterly Report, April-June 2016” (September 2016),

through June 2017, the Division of Fire reported 3,115 patients with drug overdoses who were treated by EMS with at least one dose of naloxone.²³¹

- n. Increased demands have been created on the Columbus Division of Police. As opioid-addicted persons turn to heroin and fentanyl to fuel their needs, the harm to Columbus is ongoing and promises to continue for many years. Increased illegal drug trafficking has caused a rise in other criminal activities in Columbus. Not only does this impair the quality of life for everyone in Columbus, Columbus is forced to address these crimes through police work, surveillance, field testing, lab and investigatory resources, prosecution, diversion programs, and additional manpower.

323. The Defendants' ongoing conduct produces a continuing nuisance, leading to abuse, misuse, addiction, crime, and public health issues which must be abated to prevent injury and annoyance. The Defendants' conduct directly impacted, and continues to impact, persons in Columbus, and is likely to cause significant harm in the future.

324. The Defendants knew, or reasonably should have known, that their conduct described in this Complaint would cause addiction, and otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance. But for the Defendants' individual and/or combined conduct, these harms would not have occurred.

325. The Defendants knew, or reasonably should have known, that persons would rely to their detriment on the Defendants' misrepresentations, omissions and other statements described in this Complaint.

326. It is, or should be, reasonably foreseeable to the Defendants that their conduct will

http://www.myfcph.org/pdfs/OpiateReports/DrugOD_Q2_04-06_16.pdf; Columbus Department of Public Health, "Opiate Crisis Quarterly Report, July-Sept. 2016" (December 2016), http://www.myfcph.org/pdfs/OpiateReports/DrugOD_Q3_12_21_16.pdf; Columbus Department of Public Health, "Opiate Crisis Quarterly Report, Oct.-Dec. 2016" (March 2017), http://www.myfcph.org/pdfs/OpiateReports/OpiateQuarterly_Q4_3_27_17.pdf.

²³¹ Columbus Department of Public Health, "Opiate Crisis Quarterly Report, April-June 2017" (Oct. 2017), available at <https://www.columbus.gov/publichealth/programs/Office-of-Epidemiology/Harm-Reduction/>.

continue to cause harm to Columbus in the future, and, unless abated, will otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance.

327. The Defendants acted with actual malice because the Defendants acted intentionally and/or with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm and have created an absolute nuisance.

328. The damages available to Columbus include, *inter alia*, recoupment of damages flowing from an "ongoing and persistent" public nuisance "which the government seeks to abate." *Beretta*, 768 N.E.2d at 1149-50. The Defendants' conduct is ongoing and persistent, and Columbus seeks all damages flowing from the Defendants' conduct. Columbus further seeks to abate the continuing nuisance and harm created by the Defendants' conduct into the future.

329. Columbus seeks all legal and equitable relief as allowed by law, including *inter alia*, abatement, abatement costs, available compensatory damages, and available punitive damages related to the absolute and continuing public nuisance the Defendants created, attorneys' fees and costs, and pre- and post-judgment interest.

**COUNT THREE: INJURY THROUGH CRIMINAL ACTS, O.R.C. § 2307.60
(AGAINST MANUFACTURER AND DISTRIBUTOR DEFENDANTS)**

330. Columbus incorporates by reference paragraphs 1 through 329 of this Complaint as if fully set forth herein, and further alleges as follows.

331. O.R.C. § 2307.60(A)(1) "creates a statutory cause of action for damages resulting from any criminal act," unless otherwise prohibited by law. *Jacobson v. Kafory*, 75 N.E.3d 203, 206 (Ohio 2016). "Anyone injured ... by a criminal act has ... a civil action" unless a civil action "is specifically excepted by law." O.R.C. § 2307.60(A)(1).

332. As described above, Columbus has been injured by all Defendants' actions that caused the opioid epidemic.

333. Defendants' actions and omissions were criminal and in violation of O.R.C. Chapter 2925, and more specifically Section 2925.03(A), which forbids the distribution of controlled substances.

334. Under Ohio law it is unlawful to “[b]y any means, administer or furnish to another or induce or cause another to use a controlled substance, and thereby cause serious physical harm to the other person, or cause the other person to become drug dependent,” unless an exception applies. O.R.C. § 2925.02(A)(3). The exception only applies when the drug wholesaler’s “conduct is in accordance with Chapter[...]. . . 4729. . . of the Revised Code.” O.R.C. § 2925.02(B). Because the Manufacturers and Distributors (a) caused other persons to become drug dependent and (b) failed to *inter alia* report suspicious sales, their conduct is not in compliance with Chapter 4729, and the Manufacturers and Distributors have thereby forfeited the protection provided by the exception. *See* O.R.C. § 4729.26; O.A.C. § 4729-9-16.

335. The Manufacturers and Distributors also acted in violation of 21 U.S.C. § 823(e) and 21 C.F.R. § 1301.74(b), which are incorporated into Ohio law (O.A.C. §§ 4729-9-16(L), 4729-9-28(I)).

336. The Manufacturers' and Distributors' further violations of criminal laws are described above.

337. Columbus has sustained injuries, *inter alia*, as a result of the Manufacturers' and Distributors' actions and omissions.

338. Columbus seeks all legal and equitable relief as allowed by law, including, *inter alia*, injunctive relief, full compensatory and punitive or exemplary damages, and all damages

allowed by law to be paid by the Manufacturer and Distributors, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT FOUR: FRAUD
(AGAINST ALL DEFENDANTS)

339. Columbus incorporates by reference paragraphs 1through 338 of this Complaint as if fully set forth herein, and further alleges as follows.

340. Each Defendant individually, and in concert with each other, made misrepresentations and/or omissions of facts material to Columbus, physicians treating residents of Columbus, residents of Columbus and others in order to cause them to purchase, prescribe, administer, take, consume or provide opioids as described above.

341. The Defendants had a duty not to make misrepresentations or omissions of material fact.

342. Defendants knew at the time they made the misrepresentations they were false and at the time they made the omissions they created falsity, or made the misrepresentations with utter disregard and recklessness as to their falsity.

343. The Defendants intended that Columbus, physicians treating residents of Columbus, residents of Columbus and others would rely on the misrepresentations and omissions.

344. Columbus, physicians treating residents of Columbus, residents of Columbus and others justifiably relied on the Defendants' misrepresentations and omissions.

345. Despite the exercise of due diligence, Columbus failed to discover the facts identified herein.

346. Columbus and its citizens were damaged by each Defendant's intentional and fraudulent misrepresentations and omissions of material facts.

347. Columbus seeks all legal and equitable relief as allowed by law, including, *inter alia*, full compensatory and punitive or exemplary damages, and all damages allowed by law to be paid by all Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

**COUNT FIVE: OHIO CORRUPT PRACTICES ACT, O.R.C. §§ 2923.31, et seq.
(AGAINST ALL MANUFACTURER AND DISTRIBUTOR DEFENDANTS)**

348. Columbus incorporates by reference paragraphs 1 through 347 of this Complaint as if fully set forth herein, and further alleges as follows.

349. This count is against each Manufacturer and each Distributor.

350. At all relevant times, each Manufacturer and each Distributor is and has been a "person" within the meaning of O.R.C. § 2923.31(G) who conducted the affairs of an enterprise through a pattern of corrupt activity, in violation of Chapter 2923.

351. Columbus is a "person," as that term is defined in O.R.C. §2923.31(G), that was injured in its business or property as a result of each Defendant's wrongful conduct. "Any person who is injured or threatened with injury by a violation of section 2923.32 of the Revised Code may institute a civil proceeding in an appropriate court seeking relief from any person whose conduct violated or allegedly violated section 2923.32 of the Revised Code or who conspired or allegedly conspired to violate that section" O.R.C. § 2923.34(A).

352. Manufacturers, Distributors, the KOLs, and certain Front Groups, including but not limited to (a) the American Pain Foundation, including its employees and agents; (b) the American Academy of Pain Medicine, including its employees and agents; and (c) the American Pain Society, including its employees and agents (collectively, the "Front Groups") are an association-in-fact enterprise (the "Opioid Enterprise") within the meaning of O.R.C. 2923.31(C).

353. Based on the facts alleged above, the Opioid Enterprise has been in existence for

more than 20 years, and continues through the present. The Opioid Enterprise, pursued and continues to pursue, a common purpose of causing the prescription of opioids to treat chronic pain. The Manufacturers manufactured the opioids. The Manufacturers also marketed and promoted the purported safe use of opioids to treat chronic pain through their own efforts, and through enlisting the KOLs and Front Groups. The Manufacturers enlisted the Distributors to distribute the opioids.

354. Each Manufacturer and each Distributor agreed to and did conduct and participate in the conduct of the Opioid Enterprise's affairs through a pattern of corrupt activity under O.R.C. § 2923.31(I), for the unlawful purpose of illegally selling and distributing opioids (the "Scheme"). Specifically, each Manufacturer and each Distributor engaged in dealing "in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substances Act), which is chargeable under State law and punishable by imprisonment for than one year." 18 U.S.C. §1961(1)(A). In addition, each Manufacturer and each Distributor violated 18 U.S.C. §§ 1341 and 1342 (*i.e.*, mail and wire fraud), which constitutes corrupt activity under O.R.C. § 2923.31.

355. Each Manufacturer violated O.R.C. §2925.02(A), which provides:

No person shall knowingly do any of the following:

- (1) By force, threat, or deception, administer to another or induce or cause another to use a controlled substance;
- (2) By any means, administer or furnish to another or induce or cause another to use a controlled substance with purpose to cause serious physical harm to the other person, or with purpose to cause the other person to become drug dependent;
- (3) By any means, administer or furnish to another or induce or cause another to use a controlled substance, and thereby cause serious physical harm to the other person, or cause the other person to become drug dependent[.]

356. Each Manufacturer violated O.R.C. §2925.02(A) by deceptively inducing citizens of Columbus to use opioids, inducing and causing citizens of Columbus to use opioids for the purpose of causing them to be dependent on opioids, inducing and causing residents of Columbus to use opioids and causing those persons to become drug dependent. Each Distributor violated O.R.C. § 2925.02(A)(3) because it knew or had reasonable cause to know that opioids that it sold were intended for sale or resale through illegal means.

357. Each Manufacturer and each Distributor violated O.R.C. § 2925.03(A), which provides:

No person shall knowingly do any of the following:

- (1) Sell or offer to sell a controlled substance or a controlled substance analog;
- (2) Prepare for shipment, ship, transport, deliver, prepare for distribution, or distribute a controlled substance or a controlled substance analog, when the offender knows or has reasonable cause to believe that the controlled substance or a controlled substance analog is intended for sale or resale . . .”

358. Each Manufacturer and each Distributor violated O.R.C. § 2925.03(A) by selling and distributing opioids in Columbus and because they knew or had reasonable cause to believe that the opioids they sold and distributed would be illegally resold.

359. The Manufacturers and Distributors are not protected by any exception to O.R.C. §§ 2925.02 and 2925.03 because their conduct did not comply with O.R.C. § 4729. Specifically, as set forth in the Complaint above, the Manufacturers and Distributors violated O.A.C. Section 4729-9-16 by failing to report suspicious orders. *See* O.A.C. § 4729-9-16(H)(1)(e)(i) (“The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs when discovered. Suspicious orders are those which, in relation to the wholesaler’s records as a whole,

are of unusual size, unusual frequency, or deviate substantially from established buying patterns.”). Any violation of Section 2925.03 is defined as “corrupt activity.” O.R.C. § 2923.31(I)(2)(c).

360. In addition, the Opioid Enterprise conducted its affairs through predicate acts of racketeering, as defined by 18 U.S.C. § 1961(1), constituting corrupt activity under O.R.C. § 2923.31, through:

- a. Mail Fraud: The members of the Opioid Enterprise violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via U.S. mail or commercial interstate carriers for the purpose of selling opioids.
- b. Wire Fraud: The members of the Opioid Enterprise violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, fraudulent materials by wire for the purpose of selling opioids.

361. Each particular instance of mail and/or wire fraud cannot be alleged. The precise dates and times that the Manufacturers and Distributors used the U.S. Mail and interstate wire facilities are known only to the Manufacturers and Defendants. However, based on the volume of communications that would be necessary to market opioids for sale, each Manufacturer used the U.S. Mail and interstate wire facilities to perpetrate the Scheme by, among other things:

- a. Sending marketing materials that touted the benefit of opioids to treat chronic pain and minimizing the risks of addiction to physicians, KOLs and Front Groups;
- b. Conducting telephone calls with Front Groups and KOLs to discuss the use of opioids for chronic pain;
- c. Sending thousands of e-mails to Front Groups, KOLs, doctors, medical groups, and other persons and entities involved in the distribution and marketing chains for opioids;
- d. Sending by U.S. Mail and e-mail drafts of, or comments to, publications, guidelines, or other material relating to the marketing and sale of opioids;

- e. Sending by U.S. Mail and email literature to physicians that cited the 1980 NEJM Letter-to-the-Editor as support for the contention that opioids were safe to treat chronic pain;
- f. Sending by U.S. Mail and email by the Manufacturers' sales representatives to physicians communications indicating that opioids were safe for use in treating patients for chronic pain, had low risk of addiction or other aberrant behavior and would improve patients' function;
- g. Sending communications directed to federal and State agencies and others in Ohio that misrepresented the benefits and risks of opioid use for the treatment of chronic pain; and
- h. Receiving monies through wire transfers relating to the sales of opioids.

362. In addition, each of the following Manufacturers used the U.S. Mail or interstate wire facilities to make the specific statements in furtherance of their Scheme.

363. **Purdue:** Defendant Purdue made false or misleading claims in violation of 18 U.S.C. §§ 1341 and 1343 including, but not limited to: (1) a 1998 video that cited a 1980 NEJM letter in support of the use of opioids to treat chronic pain; (2) statements made on its 2000 “Partners Against Pain” website that represented that the addiction risk of OxyContin was extremely small; (3) statements in Purdue’s Risk Evaluation and Mitigation Strategy for OxyContin indicating that “[b]ehaviors that suggest drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior”; (4) statements made on Purdue’s website and in a 2010 “Dear Healthcare Professional” letter instructing doctors to taper someone off of OxyContin to prevent problems associated with withdrawal in patients who were physically dependent opioids; (5) statements included in a 1996 sales strategy memo indicating that there is no ceiling dose for opioids for chronic pain; (6) statements on its website that abuse-resistant products can prevent opioid addiction; and (7) statements made in advertising and a 2007 book indicating that pain relief from opioids improve patients’ function and quality of life..

364. **Teva:** Defendant Teva made false or misleading claims in violation of 18 U.S.C. §§ 1341 and 1343 including, but not limited to: (1) statements made regarding Actiq and Fentora as safe and effective treatments for chronic pain, when neither drug has been approved by the FDA for treatment of chronic pain; (2) statements made promoting Actiq for use in non-cancer patients to treat such conditions as migraines, sickle-cell pain crises, and other injuries; (3) statements made promoting Actiq for use in patients who were not yet opioid-tolerant, despite its FDA-approved label indicating that the drug was for “opioid tolerant cancer patients with breakthrough cancer pain, to be prescribed by oncologist or pain specialists familiar with opioids”; (4) statements deliberately made to physicians other than oncologists, including general practitioners, promoting Actiq for off-label uses; (5) representations to pain patients that, when used properly, opioids “can be life savers and give all of us a quality of life we deserve”; (6) representations through sponsored links on Internet search engines that misrepresented the efficacy of Fentora without communicating any risk information.

365. **Endo:** Defendant Endo made false or misleading claims in violation of 18 U.S.C. §§ 1341 and 1343 including, but not limited to: (1) statements made, beginning in at least 2009, on an Endo-sponsored website, PainKnowledge.com, indicating that patients “who take opioids as prescribed usually do not become addicted”; (2) statements made on another Endo-sponsored website, PainAction.com, indicating that “most chronic pain patients do not become addicted to opioid medications that are prescribed for them”; (3) statements made on the Endo-run website, Opana.com, indicating that opioid use does not result in addiction; (4) statements made on the Endo-run website, Opana.com, indicating that opioid dependence can be addressed by dosing methods such as tapering; and (6) statements made in a publication entitled “Understanding Your Pain: Taking Oral Opioid Analgesics” suggesting that opioid doses “can be increased”

indefinitely, because “[y]ou won’t ‘run out’ of pain relief”.

366. **Janssen:** Defendant Janssen made false or misleading claims in violation of 18 U.S.C. §§ 1341 and 1343 including but not limited to: (1) statements on its website, PrescribeResponsibly.com, indicating that concerns about opioid addiction are “overestimated,” and that “true addiction occurs only in a small percentage of patients”; (2) statements included on a 2009 Janssen-sponsored website promoting the concept of opioid pseudoaddiction; (3) statements on its website, PrescribeResponsibly.com, advocating the concept of opioid pseudoaddiction; (4) statements on its website, PrescribeResponsibly.com, indicating that opioid addiction can be managed; and (5) statements in its 2009 patient education guide indicating the risks associated with limiting the dosages of pain medicines.

367. **Actavis:** Defendant Actavis made false or misleading claims in violation of 18 U.S.C. §§ 1341 and 1343 including but not limited to: (1) statements that “omit and minimize the serious risks associated with Kadian”; (2) statements that “misleadingly suggest[] that Kadian is safer than has been demonstrated”; (3) statements that “fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed[.]”; (4) statements that falsely conveyed that the risk of addiction was limited to chronic pain patients and/or patients already predisposed to abuse, addiction, and/or dysfunctional behavior; (5) statements that instructed physicians to look for signs of “pseudoaddiction” in patients; and (6) statements which suggested that the physical symptoms of opioid withdrawal could be adequately addressed by tapering.

368. **Distributors:** The Distributors violated 18 U.S.C. §§ 1341 and 1343 by sending or receiving into Columbus, or by causing to be sent and/or received into Columbus, opioids. In addition, upon information and belief, each of the Distributors falsely reported to various state

and federal government authorities that they were in compliance with state and federal laws concerning suspicious orders. Upon information and belief, these reports were transmitted by mail and/or wire. Distributors further violated 18 U.S.C. § 1341 and § 1343 by: (1) using the mail to send suspicious shipments to doctors and pharmacies in the City; (2) using the mail and/or wire communications to send invoices to doctors and pharmacies relating to the suspicious statements; and (3) using the mail and/or wire communications to send reports falsely stating that it was in compliance with federal laws concerning the distribution of opioids.

369. All of the dates of the fraudulent uses of the U.S. mail and interstate wire facilities are not yet known, but, on information and belief , based on the volume of opioid sales by the Opioid Enterprise, the number of fraudulent uses of the mail and interstate wire number in tens of thousands and continue to today.

370. The actions set forth in the Complaint above constitute a pattern of corrupt activity pursuant to O.R.C. § 2323.31.

371. The Manufacturers and Distributors have directly and indirectly conducted and participated in the conduct of the Opioid Enterprise's affairs through the pattern of corrupt activity described above, in violation of O.R.C. § 2923.32. Each of the Manufacturers orchestrated the affairs of the Enterprise and exerted substantial control over the Enterprise by, at least: (1) manufacturing the opioids; (2) determining pricing for the opioids; (3) making misleading statements about the purported benefits, efficacy, and risks of opioids to doctors, patients, the public, and others, in the form of telephonic and electronic communications, CME programs, medical journals, advertisements, and websites; (4) employing sales representatives or detailers to promote the use of opioid medications; (5) purchasing and utilizing sophisticated marketing data (*e.g.*, IMS data) to coordinate and refine the sale and distribution of opioids; (6)

employing doctors to serve as speakers at or attend all-expense paid trips to programs emphasizing the benefits of prescribing opioid medications; (7) funding, controlling, and operating the Front Groups to target doctors, patients, and lawmakers and provide a veneer of legitimacy to the Scheme; (8) retaining KOLs to tout the benefits of opioid medicines; and (9) concealing the true nature of their relationship with the other members of the Enterprise, including the Front Groups and the KOLs.

372. Each Distributor orchestrated the affairs of the Opioid Enterprise and exerted substantial control over the Enterprise by, at least: (1) shipping significant doses of opioids in Columbus, the sheer volume of which should have, or actually did, put them on notice to investigate and report such orders; (2) refusing to report such suspicious orders; (3) refusing to report suspicious prescribers; (4) failing to refuse to fill suspicious orders; (5) affirmatively misrepresenting the efforts they were taking to curb the growing epidemic; and (6) concealing the true nature of their relationship with the other members of the Enterprise.

373. As a direct and proximate result of the Manufacturers' and Distributors' corrupt activities and violations of O.R.C. § 2923.32, Columbus has been injured in its business and property in the manner set forth in the manner described above in the Complaint above.

374. Columbus seeks all legal and equitable relief as allowed by law, including, *inter alia*, injunctive relief, full compensatory and punitive or exemplary damages, including treble damages, and all damages allowed by law to be paid by all Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT SIX: CONSPIRACY, OHIO CORRUPT PRACTICES ACT,
O.R.C. §§ 2923.01, 2923.31, et seq.
(AGAINST ALL DEFENDANTS)

375. Plaintiff incorporates by reference paragraphs 1 through 374 of this Complaint, as

if fully set forth herein, and further alleges as follows.

376. This Count is against all Defendants.

377. Defendants agreed and conspired to violate O.R.C. § 2923.32(A)(1). Specifically, the Manufacturers entered into various agreements with the KOLs pursuant to which the KOLs would falsely promote the safety of opioids to treat chronic pain. The KOLS agreed to knowingly facilitate the activities of the Manufacturers and/or Distributors. The Distributors entered into agreements with the Manufacturers to distribute the opioids. The Distributors agreed to knowingly facilitate the activities of the Manufacturers by distributing opioids in violation of state and federal rules regarding suspicious orders.

378. Defendants have intentionally conspired and agreed to directly or indirectly conduct and participate in the conduct of the affairs of the enterprise through a pattern of corrupt activity. Defendants knew that their predicate acts were part of a pattern of corrupt activity and agreed to the commission of the schemes described above. The conduct constitutes a conspiracy to violate O.R.C. § 2923.32(A)(1), and constitutes a conspiracy to engage in a pattern of corrupt activity under O.R.C. § 2923.32(B), in violation of O.R.C. § 2923.01(A).

379. As direct and proximate result of the Defendants' conspiracy, the overt action taken in furtherance of that conspiracy, and violations of O.R.C. §§ 2923.01(A) and 2923.32(A)(1), Columbus has been injured in its business and property in the manner set forth in the Complaint above.

380. Columbus seeks all legal and equitable relief as allowed by law, including, *inter alia*, injunctive relief, full compensatory and punitive or exemplary damages, including treble damages, and all damages allowed by law to be paid by all Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT SEVEN: VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT (“RICO”), 18 U.S.C. § 1961(c)
(AGAINST ALL MANUFACTURER AND DISTRIBUTOR DEFENDANTS)

381. Plaintiff incorporates by reference paragraphs 1 through 380 of this Complaint, as if fully set forth herein, and further alleges as follows.

382. This count is against each Manufacturer and each Distributor.

383. At all relevant times, each Manufacturer and each Distributor is and has been a “person” within the meaning of 18 U.S.C. § 1961(3), because they are capable of holding, and do hold, “a legal or beneficial interest in property.”

384. Columbus is a “person,” as that term is defined in 18 U.S.C. § 1961(3), and has standing to sue as it was and is injured in its business and/or property as a result of the Defendants’ wrongful conduct described herein.

385. Manufacturers, Distributors, the KOLs, and the Front Groups are an association-in-fact enterprise (the “Opioid Enterprise”) within the meaning of 18 U.S.C. § 1961(4).

386. Based on the facts alleged above, the Opioid Enterprise has been in existence for more than 20 years, and continues through the present. The Opioid Enterprise, pursued and continues to pursue, a common purpose of causing the prescription of opioids to treat chronic pain. Manufacturers also marketed and promoted the purported safe use of opioids to treat chronic pain through their own efforts, and through enlisting the KOLs and Front Groups. Manufacturers enlisted the Distributors to distribute the opioids to pharmacies and doctors.

387. The Opioid Enterprise engaged in, and its activities affected, interstate and foreign commerce because it involved commercial activities across state boundaries, including but not limited to: (1) the marketing, promotion, and advertisement of opioids; (2) the advocacy at the state and federal level for change in the law governing the use and prescription of opioids;

(3) the distribution of suspicious shipments of opioids; (4) the issuance of prescriptions and prescription guidelines for opioids; and (5) the issuance of fees, bills, and statements demanding payment for prescriptions of opioids.

388. Each Manufacturer and each Distributor agreed to and did conduct and participate in the conduct of the Opioid Enterprise's affairs through a pattern of racketeering activity and for the unlawful purpose of illegally selling and distributing opioids (the "Scheme"). Specifically, each Manufacturer and each Distributor in dealing "in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substances Act), which is chargeable under State law and punishable by imprisonment for than one year." 18 U.S.C. §1961(1)(A). In addition, each Manufacturer and each Distributor violated 18 U.S.C. §§ 1341 and 1342 (*i.e.*, mail and wire fraud).

389. Each Manufacturer violated O.R.C. §2925.02(A), which provides:

No person shall knowingly do any of the following:

- (1) By force, threat, or deception, administer to another or induce or cause another to use a controlled substance;
- (2) By any means, administer or furnish to another or induce or cause another to use a controlled substance with purpose to cause serious physical harm to the other person, or with purpose to cause the other person to become drug dependent;
- (3) By any means, administer or furnish to another or induce or cause another to use a controlled substance, and thereby cause serious physical harm to the other person, or cause the other person to become drug dependent[.]

390. Each Manufacturer violated O.R.C. §2925.02(A) by deceptively inducing citizens of Columbus to use opioids, inducing and causing citizens of Columbus to use opioids for the purposes causing them to be dependent on opioids, inducing and causing citizens of Columbus to use opioids and causing those persons to become drug dependent. Each Distributor violated

O.R.C. §2925.02(A)(3) because it knew or had reasonable cause to know that opioids that it sold were intended for sale or resale through illegal means.

391. Each Manufacturer and each Distributor violated O.R.C. § 2925.03(A), which provides:

No person shall knowingly do any of the following:

- (1) Sell or offer to sell a controlled substance or a controlled substance analog;
- (2) Prepare for shipment, ship, transport, deliver, prepare for distribution, or distribute a controlled substance or a controlled substance analog, when the offender knows or has reasonable cause to believe that the controlled substance or a controlled substance analog is intended for sale or resale . . .”

392. Each Manufacturer and each Distributor violated O.R.C. § 2925.03(A) by selling and distributing opioids in Columbus and because they know or had reasonable cause to believe that the opioids they sold and distributed would be illegally resold.

393. The Manufacturer and Distributors are not protected by any exception to O.R.C. §§ 2925.02 and 2925.03 because their conduct did not comply with O.R.C. § 4729. Specifically, as set forth in the Complaint above, the Manufacturers and Distributors violated O.A.C. Section 4729-9-16 by failing to report suspicious orders. *See* O.A.C. § 4729-9-16(H)(1)(e)(i) (“The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs when discovered. Suspicious orders are those which, in relation to the wholesaler’s records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns.”). Any violation of Section 2925.03 is defined as “racketeering activity.” O.R.C. § 2923.31(I)(2)(c).

394. In addition, the Opioid Enterprise conducted its affairs through predicate acts of racketeering (18 U.S.C. § 1961(1)) through:

- a. Mail Fraud: The members of the Opioid Enterprise violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via U.S. mail or commercial interstate carriers for the purpose of opioids.
- b. Wire Fraud: The members of the Opioid Enterprise violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, fraudulent materials by wire for the purpose of selling opioids.

395. Each particular instance of mail and/or wire fraud cannot be alleged. The precise dates and times that the Manufacturers and Distributors used the U.S. Mail and interstate wire facilities are known only to the Manufacturers and Defendants. However, based on the volume of communications that would be necessary to market opioids for sale, each Manufacturer used the U.S. Mail and interstate wire facilities to perpetrate the Scheme by, among other things:

- a. Sending marketing materials that touted the benefit of opioids to treat chronic pain and minimizing the risks of addiction to physicians, KOLs and Front Groups;
- b. Conducting telephone calls with Front Groups and KOLs to discuss the use of opioids for chronic pain;
- c. Sending thousands of e-mails to Front Groups, KOLs, doctors, medical groups, and other persons and entities involved in the distribution and marketing chains for opioids;
- d. Sending by U.S. Mail and e-mail drafts of, or comments to, publications, guidelines, or other material relating to the market and sale of opioids;
- e. Sending by U.S. Mail and email literature to physicians that cited the 1980 NEJM Letter-to-the-Editor as support for the contention that opioids were safe to treat chronic pain;
- f. Sending by U.S. Mail and email by the Manufacturers' sales representatives to physicians communications indicating that opioids were safe for use in treating patients for chronic pain, had low risk of addiction or other aberrant behavior and would improve patients' function;
- g. Sending communications directed to federal and State agencies and others in Ohio that misrepresented the benefits and risks of

opioid use for the treatment of chronic pain; and

- h. Receiving monies through wire transfers relating to the sales of opioids.

396. In addition, each of the following Manufacturers used the U.S. Mail or interstate wire facilities to make the specific statements in furtherance of their Scheme.

397. **Purdue:** Defendant Purdue made false or misleading claims in violation of 18 U.S.C. §§ 1341 and 1343 including but not limited to: (1) a 1998 video that cited a 1980 NEJM letter in support of the use of opioids to treat chronic pain; (2) statements made on its 2000 “Partners Against Pain” website that represented that the addiction risk of OxyContin was extremely small; (3) statements in Purdue’s Risk Evaluation and Mitigation Strategy for OxyContin indicating that “[b]ehaviors that suggest drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior”; (4) statements made on Purdue’s website and in a 2010 “Dear Healthcare Professional” letter instructing doctors to taper someone off of OxyContin to prevent problems associated with withdrawal in patients who were physically dependent opioids; (5) statements included in a 1996 sales strategy memo indicating that there is no ceiling dose for opioids for chronic pain; (6) statements on its website that abuse-resistant products can prevent opioid addiction; and (7) statements made in advertising and a 2007 book indicating that pain relief from opioids improve patients’ function and quality of life..

398. **Teva:** Defendant Teva made false or misleading claims in violation of 18 U.S.C. §§ 1341 and 1343 including but not limited to: (1) statements made regarding Actiq and Fentora as safe and effective treatments for chronic pain, when neither drug has been approved by the FDA for treatment of chronic pain; (2) statements made promoting Actiq for use in non-cancer patients to treat such conditions as migraines, sickle-cell pain crises, and other injuries; (3)

statements made promoting Actiq for use in patients who were not yet opioid-tolerant, despite its FDA-approved label indicating that the drug was for “opioid tolerant cancer patients with breakthrough cancer pain, to be prescribed by oncologist or pain specialists familiar with opioids”; (4) statements deliberately made to physicians other than oncologists, including general practitioners, promoting Actiq for off-label uses; (5) representations to pain patients that, when used properly, opioids “can be life savers and give all of us a quality of life we deserve”; (6) representations through sponsored links on Internet search engines that misrepresented the efficacy of Fentora without communicating any risk information.

399. **Endo:** Defendant Endo also made false or misleading claims in violation of 18 U.S.C. §§ 1341 and 1343 including but not limited to: (1) statements made, beginning in at least 2009, on an Endo-sponsored website, PainKnowledge.com, indicating that patients “who take opioids as prescribed usually do not become addicted”; (2) statements made on another Endo-sponsored website, PainAction.com, indicating that “most chronic pain patients do not become addicted to opioid medications that are prescribed for them”; (3) statements made on the Endo-run website, Opana.com, indicating that opioid use does not result in addiction; (4) statements made on the Endo-run website, Opana.com, indicating that opioid dependence can be addressed by dosing methods such as tapering; and (6) statements made in a publication entitled “Understanding Your Pain: Taking Oral Opioid Analgesics” suggesting that opioid doses “can be increased” indefinitely, because “[y]ou won’t ‘run out’ of pain relief”.

400. **Janssen:** Defendant Janssen made false or misleading claims in violation of 18 U.S.C. §§ 1341 and 1343 including but not limited to: (1) statements on its website, PrescribeResponsibly.com, indicating that concerns about opioid addiction are “overestimated,” and that “true addiction occurs only in a small percentage of patients”; (2) statements included

on a 2009 Janssen-sponsored website promoting the concept of opioid pseudoaddiction; (3) statements on its website, PrescribeResponsibly.com, advocating the concept of opioid pseudoaddiction; (4) statements on its website, PrescribeResponsibly.com, indicating that opioid addiction can be managed; and (5) statements in its 2009 patient education guide indicating the risks associated with limiting the dosages of pain medicines.

401. **Actavis:** Defendant Actavis made false or misleading claims in violation of 18 U.S.C. §§ 1341 and 1343 including but not limited to: (1) statements that “omit and minimize the serious risks associated with Kadian”; (2) statements that “misleadingly suggest[] that Kadian is safer than has been demonstrated”; (3) statements that “fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed[.]”; (4) statements that falsely conveyed that the risk of addiction was limited to chronic pain patients and/or patients already predisposed to abuse, addiction, and/or dysfunctional behavior; (5) statements that instructed physicians to look for signs of “pseudoaddiction” in patients; and (6) statements which suggested that the physical symptoms of opioid withdrawal could be adequately addressed by tapering.

402. **Distributors:** The Distributors violated 18 U.S.C. §§ 1341 and 1343 by sending or receiving into Columbus, or by causing to be sent and/or received into Columbus, opioids, which have little to no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them. In addition, upon information and belief, each of the Distributors falsely reported to various state and federal government authorities that they were in compliance with state and federal laws concerning suspicious orders. Upon information and belief, these reports were transmitted by mail and/or wire. Distributors further violated 18 U.S.C. § 1341 and § 1343 by: (1) using the mail to send suspicious shipments to doctors and

pharmacies in the City; (2) using the mail and/or wire communications to send invoices to doctors and pharmacies relating to the suspicious statements; and (3) using the mail and/or wire communications to send reports falsely stating that the Distributor was in compliance with federal laws concerning the distribution of opioids.

403. All of the dates of the fraudulent uses of the U.S. mail and interstate wire facilities are not yet known, but on information and belief based on the volume of opioid sales by the Opioid Enterprise, the number of fraudulent uses of the mail and interstate wire number in tens of thousands and continue to today.

404. The acts set forth in the Complaint above constitute a pattern of racketeering activity pursuant to 18 U.S.C. § 1961(5).

405. The Manufacturers and Distributors have directly and indirectly conducted and participated in the conduct of the Opioid Enterprise's affairs through the pattern of racketeering and activity described above, in violation of 18 U.S.C. § 1962(c). Each of the Manufacturers orchestrated the affairs of the Enterprise and exerted substantial control over the Enterprise by, at least: (1) manufacturing the opioids; (2) determining pricing for the opioids; (3) making misleading statements about the purported benefits, efficacy, and risks of opioids to doctors, patients, the public, and others, in the form of telephonic and electronic communications, CME programs, medical journals, advertisements, and websites; (4) employing sales representatives or detailers to promote the use of opioid medications; (5) purchasing and utilizing sophisticated marketing data (*e.g.*, IMS data) to coordinate and refine the sale and distribution of opioids; (6) employing doctors to serve as speakers at or attend all-expense paid trips to programs emphasizing the benefits of prescribing opioid medications; (7) funding, controlling, and operating the Front Groups to target doctors, patients, and lawmakers and provide a veneer of

legitimacy to the Scheme; (8) retaining KOLs to tout the benefits of opioid medicines; and (9) concealing the true nature of their relationship with the other members of the Enterprise, including the Front Groups and the KOLs.

406. Each Distributor orchestrated the affairs of the Opioid Enterprise and exerted substantial control over the Enterprise by, at least: (1) shipping significant doses of opioids in Columbus, the sheer volume of which should have, or actually did, put them on notice to investigate and report such orders; (2) refusing to report such suspicious orders; (3) refusing to report suspicious prescribers; (4) failing to refuse to fill suspicious orders; (5) affirmatively misrepresenting the efforts they were taking to curb the growing epidemic; and (6) concealing the true nature of their relationship with the other members of the Enterprise.

407. As a direct and proximate result of the Manufacturer and Distributors' racketeering activities and violations of 18 U.S.C. § 1962(c), Columbus has been injured in its business and property in the manner set forth in the Complaint above.

408. Columbus seeks all legal and equitable relief as allowed by law, including, *inter alia*, injunctive relief, full compensatory and punitive or exemplary damages, including treble damages, and all damages allowed by law to be paid by all Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT EIGHT: VIOLATIONS OF RICO, 18 U.S.C. § 1961(d)
(AGAINST ALL DEFENDANTS)

409. Plaintiff incorporates by reference paragraphs 1 through 408 of this Complaint as if fully set forth here, and further alleges as follows.

410. This Count is against all Defendants.

411. Defendants agreed and conspired to violate 18 U.S.C. § 1962(c). Specifically, the Manufacturers entered into various agreements with the KOLs pursuant to which the KOLs

would falsely promote the safety of opioids to treat chronic pain. The KOLS agreed to knowingly facilitate the activities of the Manufacturer and Distributors. The Distributors entered into agreements with the Manufacturers to distribute the opioids. The Distributors agreed to knowingly facilitate the activities of the Manufacturers by distributing opioids in violation of state and federal rules regarding suspicious orders.

412. Defendants have intentionally conspired and agreed to directly or indirectly conduct and participate in the conduct of the affairs of the enterprise through a pattern of racketeering activity. Defendants knew that their predicate acts were part of a pattern of racketeering activity and agreed to the commission of to further the schemes described above. The conduct constitutes a conspiracy to violate 18 U.S.C. §1962(c), in violation of 18 U.S.C. §1962(d).

413. As direct and proximate result of the Defendants' conspiracy, the overt action taken in furtherance of that conspiracy, and violations of 18 U.S.C. §1962(d), Columbus has been injured in its business and property in the manner set forth in the Complaint above.

414. Columbus seeks all legal and equitable relief as allowed by law, including, *inter alia*, injunctive relief, full compensatory and punitive or exemplary damages, including treble damages, and all damages allowed by law to be paid by all Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT NINE: NEGLIGENCE
(AGAINST ALL DEFENDANTS)

415. Plaintiff incorporates by reference paragraphs 1 through 414 of this Complaint as if fully set forth here, and further alleges as follows.

416. Each Defendant had an obligation to exercise due care in distributing opioids to Columbus and its surrounding areas.

417. Each Defendant owed a duty to Columbus and its surrounding areas, and to the public health and safety in Columbus, because the injury was foreseeable, and in fact foreseen.

418. Reasonably prudent manufacturers, physicians, and distributors would have anticipated that the widespread use of opioids would cause addiction and would wreak havoc on communities.

419. The Manufacturers, the Distributors and the KOLs breached their duties to exercise due care in the business of manufacturing, promoting, and distributing opioids. Because the very purpose of these duties was to prevent the resulting harm – addiction to opioids – the causal connection between the Defendants' breach of duties and the ensuing harm was entirely foreseeable.

420. The Defendants' breach of duty caused, bears a causal connection with, and/or proximately resulted in, harm and damages to Columbus.

421. Defendants acted with actual malice or were reckless.

422. Columbus seeks all legal and equitable relief as allowed by law, including *inter alia*, injunctive relief, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

**COUNT TEN: NEGLIGENCE PER SE
(AGAINST MANUFACTURER AND DISTRIBUTOR DEFENDANTS)**

423. Plaintiff incorporates by reference paragraphs 1 through 422 of this Complaint as if fully set forth herein, and further alleges as follows.

424. O.R.C. §§ 2925.02, 2925.03, 3767.01, 4729.35, and O.A.C. §§ 4729-9-12, 4729-9-16, 4729-9-28, are public safety laws. Each Manufacturer and Distributor had a duty under, *inter alia*, these laws to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids. The Manufacturer's and

Distributors' violations of the law constitute negligence per se.

425. It was foreseeable that the breach of their duties would result in the damages sustained by Columbus.

426. The Manufacturers and Distributors breached their duties.

427. The Manufacturers' and Distributors' breach of statutory and regulatory duties caused, bears a causal connection with, and proximately resulted in, harm and damages to Columbus.

428. The Manufacturers and Distributors acted with actual malice or were reckless.

429. Columbus seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, compensatory and punitive damages, and all damages allowed by law to be paid by the Manufacturers and Distributors, attorneys' fees and costs, and pre- and post-judgment interest.

**COUNT ELEVEN: DECEPTIVE TRADE PRACTICES ACT, O.R.C. § 4165.01, et seq.
(AGAINST MANUFACTURER DEFENDANTS AND KOL DEFENDANTS)**

430. Columbus incorporates by reference paragraphs 1 through 429 of this Complaint as if fully set forth herein, and further alleges as follows.

431. The Manufacturers and KOLs have committed deceptive trade practices by causing a likelihood of confusion or misunderstanding as to affiliation, or connection with another, in violation of O.R.C. § 4165.02(A)(3).

432. The Manufacturers and KOLs have also committed deceptive trade practices by representing, and continuing to represent, that the Manufacturers' opioids have characteristics, uses, or benefits that they do not have, in violation of O.R.C. § 4165.02(A)(7).

433. Purdue's deceptive trade practices include, but are not limited to, (1) making misleading statements; (2) funding, controlling, and operating the Front Groups, including the

American Pain Foundation and the Pain & Policy Studies Group; (3) participating in the Pain Care Forum, a coalition of drug makers, trade groups, and nonprofit organizations that, collectively, spent hundreds of millions of dollars lobbying against opioid-related measures; (4) retaining the KOLs to tout the benefits of opioid medicines; and (5) concealing the true nature of its relationship with the other Manufacturers and KOLs.

434. Teva's deceptive trade practices include, but are not limited to, (1) making misleading statements, particularly regarding the promotion of opioids for off-label uses; (2) funding, controlling, and operating the Front Groups, including the American Pain Foundation and the Pain & Policy Studies Group; (3) sponsoring a series of CME programs which claimed that opioid therapy has been shown to reduce pain and depressive symptoms; (4) supporting and sponsoring guidelines indicating that opioid medications are effective and can restore patients' quality of life; (5) participating in the Pain Care Forum, a coalition of drug makers, trade groups, and nonprofit organizations that, collectively, spent hundreds of millions of dollars lobbying against opioid-related measures; (6) retaining the KOLs to tout the benefits of opioid medicines; and (7) concealing the true nature of its relationship with the other Manufacturers and KOLs.

435. Endo's deceptive trade practices include, but are not limited to, (1) making misleading statements; (2) sponsoring a 2009 National Initiative on Pain Control CME program which promoted the concept of pseudoaddiction; (3) funding, controlling, and operating the Front Groups, including the American Pain Foundation and the Pain & Policy Studies Group; (3) sponsoring a series of CME programs which claimed that opioid therapy has been shown to reduce pain and depressive symptoms; (4) supporting and sponsoring guidelines indicating that opioid medications are effective and can restore patients' quality of life; (5) participating in the Pain Care Forum, a coalition of drug makers, trade groups, and nonprofit organizations that,

collectively, spent hundreds of millions of dollars lobbying against opioid-related measures; (6) retaining the KOLs to tout the benefits of opioid medicines; and (7) concealing the true nature of its relationship with the other Manufacturers and KOLs.

436. Janssen's deceptive trade practices include, but are not limited to, (1) making misleading statements; (2) funding, controlling, and operating Front Groups, including the Pain & Policy Studies Group; (3) supporting and sponsoring guidelines indicating that opioid medications are effective and can restore patients' quality of life; (4) sponsoring, funding, and editing a website which features an interview indicating that opioid medications can improve patients' function; (5) participating in the Pain Care Forum, a coalition of drug makers, trade groups, and nonprofit organizations that, collectively, spent hundreds of millions of dollars lobbying against opioid-related measures; (6) retaining the KOLs to tout the benefits of opioid medicines; and (7) concealing the true nature of its relationship with the other Manufacturers and KOLs.

437. Actavis' deceptive trade practices include, but are not limited to, (1) making misleading statements; (2) funding, controlling, and operating the Front Groups, including the American Pain Foundation and the Pain & Policy Studies Group; (3) sponsoring a series of CME programs which claimed that opioid therapy has been shown to reduce pain and depressive symptoms; (4) supporting and sponsoring guidelines indicating that opioid medications are effective and can restore patients' quality of life; (5) retaining the KOLs to tout the benefits of opioid medicines; and (6) concealing the true nature of its relationship with the other Manufacturers and KOLs.

438. The KOLs' deceptive trade practices include, but are not limited to, (1) making misleading statements about the purported benefits, efficacy, and low risks of opioids; (2)

holding themselves out as independent, when in fact there are systematically linked to and funded by opioid drug manufacturers; and (3) concealing the true nature of their relationship with the Manufacturers.

439. Columbus and its residents have been injured by reason of the Manufacturers' and the KOLs' violations of O.R.C. Chapter 4165.

440. Columbus seeks all legal and equitable relief as allowed by law, including *inter alia*, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Manufacturers and the KOLs, attorneys' fees and costs, and pre- and post-judgment interest.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays that this Court grant the following relief:

1. Enter Judgment in favor of the City of Columbus in a final order against each of the Defendants;

2. Enjoin the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with them, from engaging in the unlawful manufacture, marketing, distribution and sales of prescription opioid pills and ordering a permanent injunction;

3. Order that the Defendants compensate the City for its past and future costs to abate the continuing and absolute public nuisance caused by the opioid epidemic;

4. Impose an award of actual and triple the actual damages the City has sustained as a result of Defendants' violations of the Ohio Corrupt Practices Act and the Racketeer Influenced

and Corrupt Organizations Act, and an award of the City's reasonable Attorney's fees incurred in prosecuting those violations;

5. Award the City its damages caused by abating the opioid epidemic, and to be incurred, including, but not limited to, (a) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments/services for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (b) costs for providing treatment, counseling, and rehabilitation services; (c) costs for providing treatment of infants born with opioid-related medical conditions; (d) costs associated with law enforcement and public safety relating to the opioid epidemic; and (e) any other costs, expenses or damages caused by the Defendants' conduct described above;

6. Order the Defendants to fund an "abatement fund" for the purposes of abating the opioid nuisance;

7. Order Defendants to fund a "treatment fund" for the purposes of treating those throughout Columbus who have become addicted or otherwise injured as a result of the oversaturation of opioids created by the Defendants;

8. Award judgment requiring Defendants to pay punitive and exemplary damages; and

9. Grant Columbus court costs, including reasonable attorneys' fees, pre-judgment and post-judgment interest, and all other relief as provided by law and/or as the Court deems appropriate and just.

CITY OF COLUMBUS, DEPARTMENT OF LAW
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JURY DEMAND

Columbus demands that this case be tried to a jury comprised of the maximum number permitted by law.

s/Michael H. Carpenter
One of the Attorneys for the
City of Columbus